JUL 10 2014

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
Alexandria Division

INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 49 HEALTH & WELFARE FUND, on behalf of itself and all others similarly situated,

Plaintiff,

v.

PFIZER, INC., G.D. SEARLE LLC, and PFIZER ASIA PACIFIC PTE. LTD.,

Defendants.

Civil Action No. 1:14-cv-865 GBL/IDD

COMPLAINT

I. INTRODUCTION

1. In 2008, the United States Court of Appeals for the Federal Circuit ruled that a Pfizer patent for its blockbuster painkiller Celebrex was invalid. The court ruled that the patent, for methods of using the active pharmaceutical ingredient celecoxib to treat inflammation-related disorders, was not patentably distinct from earlier Pfizer patents (one that covered the celecoxib compound itself and the other formulations of celecoxib) that already disclosed the use of celecoxib to reduce inflammation. Patent exclusivity for Celebrex would therefore not extend beyond expiration of the compound patent on May 30, 2014.

2. To avoid the consequences of the Federal Circuit ruling invalidating its patent and allowing earlier competition into the market for Celebrex, Pfizer implemented a scheme to unlawfully prolong patent protection for celecoxib well beyond May 30, 2014.

3. First, Pfizer sought from the United States Patent and Trade Office ("PTO") reissuance of the defunct method-of-use patent by claiming that its earlier applications for the

patent contained unintentional "errors" needing "correction" in light of the Federal Circuit ruling. This was false and Pfizer knew it. And for over four years – from September of 2008 until March of 2013 – Pfizer bombarded the PTO with false information, deflective arguments and voluminous irrelevant materials. After repeated rejections, Pfizer's efforts were met with even further Pfizer submissions, and after Pfizer resorted to a further subterfuge to recast most claims to cause the examiner to overlook the true purpose of the reissue claim, the PTO finally succumbed to Pfizer's onslaught of false information and trickery, and allowed the reissue patent.

4. Second, in 2013 Pfizer used the fraudulently obtained reissue patent to prosecute sham litigation against would-be makers of generic Celebrex. Not only did Pfizer know that it had procured its reissue patent by fraud, it also knew that (independent of the fraud it had waged on the PTO) a court would find that the reissue patent had been erroneously granted and was invalid for non-obviousness double-patenting over Pfizer's earlier celecoxib patent. But Pfizer's goal was not to win this sham litigation; it was simply to use the lawsuit to delay would-be generic makers' entry efforts, and to have a lawsuit pending to serve as a vehicle for later settlements that would buy Pfizer additional exclusivity beyond May 2014.

5. Pfizer's scheme worked. It procured the reissue patent through fraud and trickery. It used that patent to file a sham lawsuit in March 2013. And although in that lawsuit the court granted summary judgment against Pfizer, before the actual judgment could enter, Pfizer used the pending sham lawsuit to "settle" with first-to-file, would-be generic manufacturer Teva Pharmaceuticals USA, Inc. ("Teva") under terms providing that Teva would not launch its competing generic product until December 2014 (six months after May 30, 2014). As a result, purchasers of prescription drugs are now paying, and will continue to pay, supracompetitive

prices for Celebrex, imposing antitrust overcharges on purchasers of many hundreds of millions of dollars even though the only valid celecoxib patents have already expired.

6. This suit is brought on behalf of a proposed Class that is buying celecoxib at supracompetitive prices. The class seeks to hold Pfizer accountable for its strategic manipulation of the patent review and judicial processes in violation of federal antitrust law.

II. PARTIES

7. Plaintiff International Union of Operating Engineers Local 49 Health & Welfare Fund ("IUOE Local 49 Fund") is an employee welfare benefit plan. The IUOE Local 49 Fund's office, from which it pays medical benefits for prescription drugs, is located at 3001 Metro Drive, Suite 500, Bloomington, MN 55425. The IUOE Local 49 Fund has purchased Celebrex, other than for re-sale (and will purchase generic Celebrex other than for re-sale once it becomes available), at supra-competitive prices during the Class Period (as defined herein) and has thereby been injured.

8. Defendant Pfizer Inc. is a Delaware corporation, having its principal place of business at 235 East 42 Street, New York, New York, 10017.

9. Defendant G.D. Searle LLC ("Searle") is a Delaware limited liability company with its principal place of business at 235 East 42 Street, New York, New York, 10017. Searle LLC is a wholly-owned indirect subsidiary of Pfizer Inc. Searle holds an approved New Drug Application, NDA No. 20-998, for celecoxib capsules, 50 mg, 100 mg, 200 mg, and 400 mg dosage strengths, which it sells under the name Celebrex. Searle is the named assignee of the '048 patent.

10. Defendant Pfizer Asia Pacific Pte. Ltd. ("PAP") is a private limited company organized and existing under the laws of Singapore, with its principal place of business at 31 Tuas South Avenue 6, Singapore 637578. PAP is a wholly-owned indirect subsidiary of Pfizer

Inc. PAP is the holder of certain rights under the '048 patent, including an exclusive license to manufacture and sell Celebrex.

11. Defendants Pfizer Inc., Searle and PAP are referred to collectively herein as "Pfizer." Pfizer is engaged in the worldwide marketing, production, and distribution of pharmaceutical products, including in this district.

12. All of Pfizer's actions described in this complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Pfizer's officers, agents, employees, or other representatives while actively engaged in the management of Pfizer's affairs (or that of its predecessors-in-interest) within the course and scope of their duties and employment, and/or with Pfizer's actual, apparent, and/or ostensible authority.

III. JURISDICTION AND VENUE

13. This action arises under state antitrust law, sections 1 and 2 of the Sherman Act, 15 U.S.C. §§ 1 and 2, and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover threefold damages, interest, costs of suit and reasonable attorneys' fees for the injuries sustained by Plaintiff and members of the class (defined below) resulting from Pfizer's unlawful foreclosure of the United States market for celecoxib. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a) and 1407, and 15 U.S.C. § 15.

14. Venue is proper in this district pursuant to 15 U.S.C. §§ 15(a), 22 and 28 U.S.C. §§ 1391(b), (c), and (d) because during the class period, each of the defendants resided, transacted business, were found, or had agents in this district, and a substantial portion of the alleged activity affected interstate trade and commerce and has been carried out in this district.

15. Pfizer's conduct, as described in this complaint, were within the flow of, were intended to have a substantial effect on, and did have a substantial effect on, the interstate commerce of the United States, including in this district.

16. During the class period, Pfizer manufactured, sold and shipped Celebrex in a continuous and uninterrupted flow of interstate commerce. Pfizer's conduct had a direct, substantial, and reasonably foreseeable effect on interstate commerce.

17. This Court has personal jurisdiction over each defendant. Each defendant – throughout the United States and including in this district – has transacted business, maintained substantial contacts, or committed overt acts in furtherance of their illegal scheme. The scheme has been directed at, and has had the intended effect of, causing injury to persons residing in, located in, or doing business throughout the United States, including in this district.

IV. REGULATORY BACKGROUND

18. Brand drug companies can, and do, obtain valid patents that cover their new prescription drug products. Such patents encourage discovery and development of new medicines, providing protection from competition by other drug companies for a length of time set under a statute by Congress.

19. Once the lawful periods of exclusivity expire on brand products, generic companies can seek FDA approval to sell generic versions of the brand, allowing the generic companies to manufacture generic products that are just as safe and effective, but far less expensive than, the brand. The medication becomes affordable for all, and purchasers are no longer burdened by the high cost of the brand drug.

20. At root, then, is a basic principle in the American system of access to prescription drugs that addresses these goals and paves the way for both new and more affordable drugs. It is this: brand names have a statutory period of time to charge very high prices for medications that, in fact, cost little to manufacture, but it is a limited period, after which generic companies can compete with low-cost substitutes. And from this basic principle emerges two basic rules: that a brand company should not deceive the U.S. patent office in order to procure an invalid patent to

delay entry of less expensive, but therapeutically equivalent, generic medications, and that a brand company should not prosecute infringement lawsuits that have no reasonable likelihood of succeeding.

21. This case involves a breach by one large brand drug company, Pfizer, of these basic rules.

A. The Competitive Effects of AB-Rated Generic Competition

22. Generic versions of brand name drugs contain the same active ingredients, and are determined by the FDA to be just as safe and effective as their brand name counterparts. The only material difference between generic drugs and their corresponding brand name versions is their price. Because generic versions of a corresponding brand drug product are commodities that cannot be differentiated, the primary basis for generic competition is price. Typically, generics are at least 25% less expensive than their brand name counterparts when there is a single generic competitor, and this discount typically increases to 50% to 80% (or more) when there are multiple generic competitors on the market for a given brand. Consequently, the launch of a generic drug usually results in significant cost savings to all drug purchasers.

23. Since passage of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act, every state has adopted substitution laws that either require or permit pharmacies to substitute AB-rated generic equivalents for brand prescriptions (unless the prescribing physician has specifically ordered otherwise). Substitution laws and other institutional features of pharmaceutical distribution and use create the economic dynamic that the launch of AB-rated generics results both in rapid price decline and rapid sales shift from brand to generic purchasing. Once a generic equivalent hits the market, the generic quickly captures sales of the corresponding brand drug, often capturing 80% or more of the market within the first six months. This results in a loss of revenue for the brand drug company, but dramatic savings for the

American public. In a recent study, the Federal Trade Commission ("FTC") found that on average, within a year of generic entry, generics had captured 90% of corresponding brand drug sales and (with multiple generics on the market) prices had dropped 85%. As a result, competition from generic drugs is viewed by brand name drug companies, such as Pfizer, as a grave threat to their bottom lines.

24. Generic competition enables all members of the proposed Class to: (a) purchase generic versions of the drug at substantially lower prices; and/or (b) purchase the brand drug at a reduced price.

25. Until a generic version of the brand drug enters the market, however, there is no bioequivalent generic drug to substitute for and compete with the brand drug, and therefore the brand manufacturer can continue to profitably charge supracompetitive prices. Brand manufacturers, such as Pfizer, are well aware of generics' rapid erosion of their brand sales. Brand manufacturers thus seek to extend their monopoly for as long as possible, sometimes resorting to any means possible – including illegal means.

1. The first AB-rated generic is priced below the brand

26. Experience and economic research show that the first generic manufacturer to launch prices its product below the prices of its brand counterpart. Every state either requires or permits a prescription written for the brand drug to be filled with an AB-rated generic. Thus, the first generic manufacturer almost always captures a large share of sales from the brand form of the molecule. At the same time, there is a reduction in average price paid for a prescription for the molecule.

27. Pursuant to the Hatch-Waxman Amendments, the first generic manufacturer to file an abbreviated new drug application ("ANDA") containing a Paragraph IV certification (discussed below) receives 180 days of market exclusivity. This means that other generic

manufacturers will not be able to launch their own generic products for at least six months after the first generic – known as the "first filer" – launches its product.

28. During the exclusivity period, the first filer is the only ANDA-approved generic manufacturer on the market. As recognized by the Supreme Court, it is often the case that most of a first filer's profits with respect to an ANDA product are earned during the exclusivity period.[1]

29. If the only versions of a drug on the market are the brand and the first filer's product, then the first filer prices its product below the brand product, but not as low as if it were facing competition from other generics. Since in these circumstances the first filer's product may compete only with the brand, and because the brand company rarely drops the brand price to match the first filer, the first filer does not face the kind of price competition it will when additional generic products are available.

2. Later generics drive prices down further

30. When multiple generic competitors enter the market, competition accelerates and prices drop to their lowest levels. Multiple generic sellers typically compete vigorously with each other over price, driving prices down toward marginal manufacturing costs.

31. According to the FDA and the FTC, the greatest price reductions are experienced when the number of generic competitors goes from one to two. In that situation, there are two commodities that compete on price. Some typical estimates are that a single generic launch results in a near term retail price reduction of at least 10%, but that with two generic entrants near term retail price reduction is about 50%.

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[1] *See Federal Trade Comm'n v. Actavis*, 133 S.Ct. 2223, 2229 (2013).

32. Soon after generic competition begins, the vast majority of the sales formerly enjoyed by the brand shift to generic sellers. In the end, total payments to the brand manufacturer of the drug decline to a small fraction of the amounts paid prior to generic entry. Although generic drugs are chemically identical to their brand counterparts, they are typically sold at substantial discounts from the brand price. According to the Congressional Budget Office, generic drugs save consumers an estimated $8 to $10 billion a year at retail pharmacies. Even more billions are saved when hospitals use generics.

B. The regulatory structure for approval of new drugs.

33. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), drug companies who wish to sell a new drug product must file a New Drug Application ("NDA") with the FDA. An NDA must include submission of specific data concerning the safety and effectiveness of the drug, as well as any information on applicable patents.

34. The FDA may not approve an NDA if the data and test results provided fail to show that the drug is safe or if there is a lack of substantial evidence that the drug will be effective to treat the conditions suggested in the proposed labeling. The FDA approves new drugs based on their ability to satisfy the minimum regulatory requirements; namely, show that they are safe and effective to treat a particular indication. New drug applicants are not required to, and usually do not try to, show that their new drug product is better than other similar, already approved, products.

C. Patent protection for brand drugs.

1. Patent portfolios for blockbuster drugs.

35. There is a predictable pattern to the way brand drug companies develop their patent portfolios for blockbuster drugs. The first group of patents in the brand drug company's portfolio for the drug may reflect a genuine technological breakthrough that may later contribute

to the success of the drug; these initial patents usually cover the active compound in a prescription drug or a particular pharmaceutical composition and are correspondingly robust.

36. After filing applications for the original patents, the company continues its research and development efforts to develop a drug product that could, eventually, be approved by the FDA. As the company's research matures, the patent filings continue, often for narrow modifications relating to specific formulations, methods of using the drug, or processes for creating the drug product disclosed in the original patent filings. But the original patent filings are now in the "prior art" and thus limit the scope of follow on patents that can be obtained. New patents can be obtained for features of the drug only if the brand drug company can show that the new features are non-obvious improvements over the growing body of prior art, which includes patents and printed publications, among other things. And often methods of using earlier inventions are disclosed by earlier compound or composition patents. Over time, as the number of patent filings for the drug grows, so does the volume of prior art beyond which the brand drug company must show non-obvious improvements.

37. Patents present, at minimum, obstacles for would-be generic competitors to design around. Some patents broadly cover a drug's active ingredient and – if valid and enforceable – may prove impossible to design around while meeting the FDA's criteria for equivalent generics. While approved generic versions of the brand product may be able to enter the market before all patents expire, once all the valid patents covering its blockbuster drug have expired, the brand drug company has no lawful means of preventing competitors from entering the market.

38. Therefore, a typical patent portfolio for a brand drug has its most significant patents issuing first; over time, the newly issued patents generally become increasingly narrow

and more difficult to obtain. Even if the narrower coverage is obtained, these later-issuing patents are more vulnerable to attack as invalid for covering subject matter that is old or obvious, and the narrower coverage is more easily designed around by would-be generics.

2. Types of patents and patent applications.

a. Restriction requirements.

39. Generally, each patent should cover only one invention or kind of invention. If one application claims two or more independent and distinct inventions, the PTO may require that the application be restricted to only one invention. Restriction is the practice of requiring an applicant to choose a single invention for examination when two or more independent inventions and/or two or more distinct inventions are claimed in an application.

40. An applicant may later choose to pursue the "restricted-out" inventions in separate applications.

b. Divisional versus continuation-in-part applications.

41. To respond to a restriction requirement, an applicant must decide which invention to pursue in the current application and whether to pursue the other inventions in new applications. If an applicant decides to file separate applications for the other inventions, the applicant must decide what type of application to file: divisional, continuation, or continuation-in-part. Depending on his choice, there are different consequences.

42. A divisional application is a later application for an independent or distinct invention, carved out of a pending application and disclosing and claiming *only* subject matter disclosed in the earlier/parent application. While a divisional application may depart from the phraseology used in the parent application, there may be no departure in substance or variation in the disclosure that would amount to "new matter."

43. A divisional application is often filed as a result of a restriction requirement made by the examiner. A divisional application literally claims some of the exact same subject matter that was "restricted out" by the applicant's decision to pursue other subject matter in the original application. The divisional application claims the benefit of the parent patent application. As a result, because the divisional application states no new matter, the date of filing of the predecessor application is the claimed date of the invention. The divisional application should set forth at least the portion of the earlier disclosure that is germane to the invention as claimed in the divisional application.

44. One advantage to choosing to file a divisional application in response to a restriction requirement is that divisional applications ordinarily cannot be rejected as obvious in light of an earlier patent application by the same applicant (called an "obviousness-type double patenting rejection."). An applicant cannot obtain additional patent protection based on claims in a later patent unless those claims are "patentably distinct" from claims in the applicant's earlier patent(s).[2] A later patent claim is not "patentably distinct" from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim.[3] As an example, a claim to a method of using a composition is not patentably distinct from an earlier claim to the identical composition in a patent disclosing an identical use.

45. Congress created an exception for divisional applications that are filed in response to a restriction requirement in 35 U.S.C.§ 121 ("Section 121"):

> If two or more independent and distinct inventions are claimed in one application, the Director may require the application to be restricted to one of the inventions. If the other invention is made the subject of a *divisional* application which complies with the requirements of section 120 it shall be entitled to the benefit of the

[2] *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 967 (Fed. Cir. 2001).

[3] *Id.* (citing *In re Longi*, 759 F.2d 887, 896 (Fed. Cir. 1985)).

> filing date of the original application. A patent issuing on *an application with respect to which a requirement for restriction under this section has been made, or on an application filed as a result of such a requirement*, shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application or against the original application or any patent issued on either of them, if the *divisional* application is filed before the issuance of the patent on the other application. The validity of a patent shall not be questioned for failure of the Director to require the application to be restricted to one invention.

(emphasis added).

46. An application is not entitled to this "safe harbor" provision unless the examiner "require[s] the application to be restricted to one of the inventions."

47. A continuation-in-part application is an application filed during the lifetime of an earlier application, it may repeat some substantial portion or all of the earlier application but it also adds matter not disclosed in the earlier application. As the name implies, a continuation-in-part application partly continues subject matter from an earlier application *but also adds new subject matter.*

48. The key, then, between a divisional application and a continuation-in-part application is whether the application claims something new. In terms of choosing how to respond to a restriction requirement, each has its own advantage. Filing a continuation-in-part application allows the applicant to put his arms around (*i.e.*, obtain patent protection for) more material, but it leaves the applicant open to potential obviousness rejections based on the original application. In contrast, filing a divisional application restricts the applicant to only the matter identified in the original application, but eliminates the threat of an obviousness rejection.

c. Original versus reissued patents.

49. A reissue patent may be filed pursuant to 35 U.S.C. § 251 ("Section 251") after the grant of an original patent to correct an error in the original patent where such error would

render the original patent wholly or partially inoperative or invalid. Once a patent is reissued, the original patent must be surrendered.

50. The PTO treats an application for a reissue patent as a new patent application. It must satisfy the same procedural and substantive patentability requirements as an original patent application.

51. A reissue application is filed to correct an error in the patent, where, as a result of the error, the patent is deemed wholly or partly inoperative or invalid. An error in the patent arises out of an error in conduct which was made in the preparation and/or prosecution of the application which became the patent. "[N]ot every choice that produces inoperativeness or invalidity by reason of a specification, drawing, or claiming problem (within the meaning of section 251) can qualify. Only choices based on 'error' count."[4] The most common bases for filing a reissue application are: (a) the claims are too narrow or too broad; (b) the disclosure contains inaccuracies; (c) applicant failed to or incorrectly claimed foreign priority; and (d) applicant failed to make reference to or incorrectly made reference to prior co-pending applications.

3. Brand companies may list patents (original or reissued) covering brand drugs in the Orange Book.

52. To notify other drug manufacturers, a manufacturer of a new drug product must tell the FDA about patents that it believes cover its drug products. The FDA publishes a list of those patents in the publicly available "Orange Book." Patents issued after NDA approval may be listed in the Orange Book within 30 days of issuance. Once patents are listed in the Orange Book, potential generic competitors are on notice regarding the patents that are claimed to relate to the brand name drug.

[4] *In re Dinsmore*, No. 13-1637, slip op. at 8 (Fed. Cir. June 10, 2014).

53. The brand name drug manufacturer can list its patents in the Orange Book by filing a Form 3542 with the FDA. Under the FDA rules, the branded manufacturer is only permitted to list patents that are *reasonably enforceable.* Form 3542 expressly asks the applicant whether the drug presents a "No Relevant Patent" situation (*i.e.*, a situation where there are no patents that could be *reasonably asserted* in an infringement lawsuit). Form 3542 likewise requires the signatory to affirm, under penalty of perjury, that all the patent information submitted to the FDA on each patent that claims the drug substance, drug product, or method of use that is the subject of the approved NDA or supplement is complete and accurate.

54. The FDA relies completely on the manufacturer's truthfulness about patent validity and applicability, as it does not have the resources or authority to verify the manufacturer's representations. The FDA performs only a ministerial act in listing the patents identified by the manufacturer in the Orange Book.

D. The regulatory approval process for generic drugs.

1. The Hatch-Waxman Amendments sought to expedite introduction of generic drugs.

55. In 1984, Congress passed the Hatch-Waxman Amendments to the FDCA. The Hatch-Waxman Amendments were designed to speed the introduction of low-cost generic drugs to market by permitting generic manufacturers to file abbreviated new drug applications (ANDAs) that rely on the scientific findings of safety and effectiveness included in the brand name drug manufacturer's original NDA, requiring only a showing that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand name drug. The premise – codified by Congress and implemented by the FDA for the past thirty years – is that two drug products that contain the same active pharmaceutical ingredient, in

the same dose, delivered in the same way, and are absorbed into the blood stream at a similar rate over a similar period of time are expected to be equally safe and effective.

56. At the same time, the Hatch-Waxman Amendments also sought to protect pharmaceutical companies' incentives to create new and innovative products, by, among other things, permitting a brand company to file a *legitimate* patent infringement lawsuit against a generic before the generic actually brought its product to market.

57. The Hatch-Waxman Amendments achieved both goals, advancing substantially the rate of generic product launches, and ushering in an era of historic high profit margins for brand name pharmaceutical companies. In 1983, before the Hatch-Waxman Amendments, only 35% of the top-selling drugs with expired patents had generic alternatives; by 1998, nearly all did. In 1984, prescription drug revenue for brand and generic drugs totaled $21.6 billion, with generic drugs accounting for 18.6% of prescriptions. By 2013, total prescription drug revenue had soared to over $329 billion, with generic drugs accounting for 84% of prescriptions.

2. Hatch-Waxman encourages generics to challenge questionable patents.

58. The Hatch-Waxman Amendments also created a mechanism to resolve patent disputes between brand and generic manufacturers before generic products launched, in the hopes of resolving patent challenges in advance of the generic launch (so that the generic's launch will not be unnecessarily delayed while patent squabbles ensue). The Amendments permitted a brand manufacturer to sue a generic for patent infringement even if their products had not launched yet.

59. Once one or more patents are listed in the Orange Book, a generic manufacturer must certify that the generic drug addressed in its ANDA will not infringe any of those patents to obtain FDA approval of an ANDA. A generic manufacturer can make one of four certifications:

i. that no patent for the brand name drug has been filed with the FDA;

ii. that the patent for the brand name drug has expired;

iii. that the patent for the brand name drug will expire on a particular date and the generic company does not seek to market its generic product before that date; or

iv. that the patent for the brand name drug is invalid or will not be infringed by the generic manufacturer's proposed product.

60. If a generic manufacturer files a Paragraph IV certification, a brand name manufacturer can sue the ANDA applicant for patent infringement. If the brand name manufacturer initiates a patent infringement action against the generic filer within 45 days of receiving notification of the Paragraph IV certification ("Paragraph IV Litigation"), the FDA will not grant final approval to the ANDA until the earlier of (a) the passage of 30 months, or (b) the entry of a final judgment on a decision by a court that the patent is invalid or not infringed by the generic manufacturer's ANDA. Until one of those conditions occurs, the FDA cannot authorize the generic manufacturer to go to market with its product. The FDA may grant an ANDA tentative approval when it determines that the ANDA would otherwise be ready for final approval but for the 30-month stay.

61. The brand could file patent infringement claims more than 45 days after receiving the Paragraph IV certification, but doing so would not trigger the automatic stay of approval.

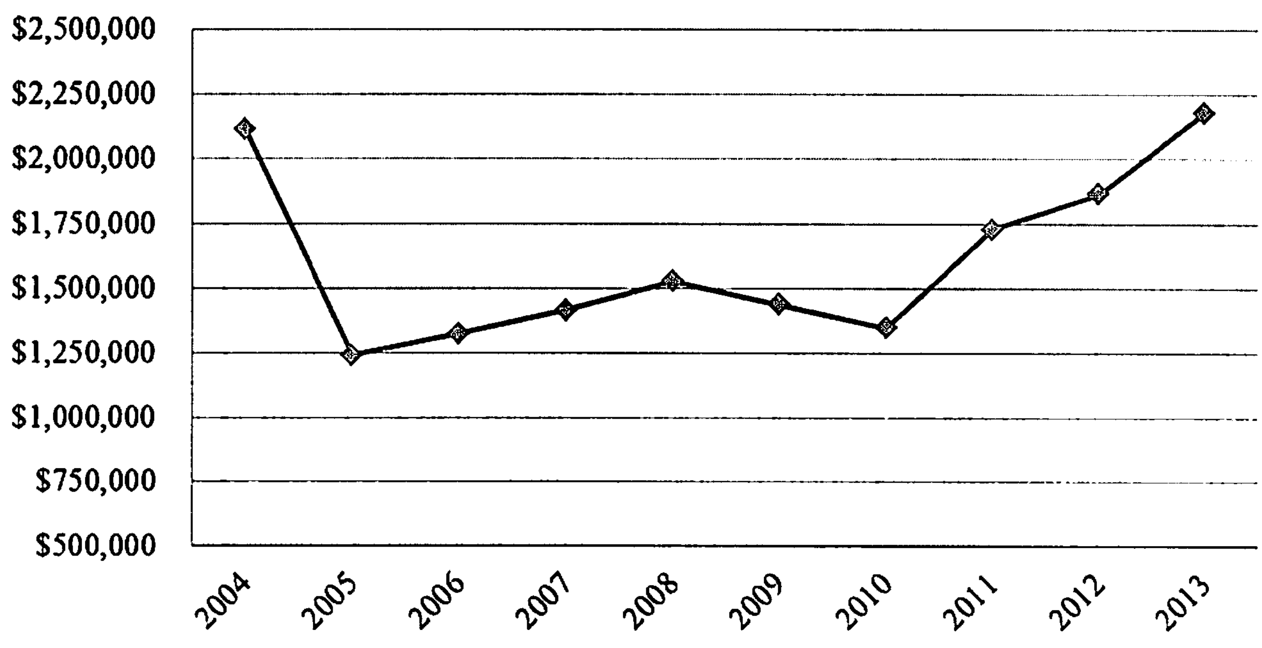
V. FACTUAL ALLEGATIONS

A. The FDA approves Pfizer's Celebrex.

62. Pfizer manufactures and sells the prescription drug celecoxib under the brand name Celebrex, a non-steroidal anti-inflammatory drug ("NSAID") approved to treat osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, acute pain, and primary dysmenorrhea. Celebrex is one of the most widely prescribed drugs in the world; last year, U.S. sales of Celebrex topped $2 billion.

Year	Annual Retail Sales
2004	$ 2,114,734
2005	$ 1,241,574
2006	$ 1,326,177
2007	$ 1,416,084
2008	$ 1,526,818
2009	$ 1,437,539
2010	$ 1,349,833
2011	$ 1,728,618
2012	$ 1,866,967
2013	$ 2,183,246

Annual Retail Sales of Celebrex in the U.S., 2004 - 2013



63. Pfizer first applied for approval to market Celebrex on June 29, 1998. Pfizer submitted NDA 20-998 seeking FDA approval to market celecoxib capsules in 100 mg and 200

mg strengths. The FDA approved 100 mg and 200 mg strengths of Celebrex for the relief of the signs and symptoms of osteoarthritis and rheumatoid arthritis in adults on December 31, 1998.

64. The FDA later approved Pfizer's supplemental NDAs to market Celebrex for the management of acute pain in adults and the treatment of primary dysmenorrhea (on October 10, 2001) and for the relief of signs and symptoms of ankylosing spondylitis (on July 29, 2005). The FDA also approved 400 mg capsules (on August 29, 2002) and 50 mg capsules (on December 15, 2006).

65. Pfizer submitted an additional NDA for Celebrex, NDA 21-156, on June 24, 1999, seeking approval to market Celebrex for the reduction of the number of adenomatous colorectal polyps in familial adenomatous polyposis ("FAP") patients. The FDA approved that indication on December 23, 1999. Pfizer later requested that the FDA withdraw the FAP indication for Celebrex from the market on February 2, 2011, and the FDA withdrew its approval of that indication effective June 8, 2012.

B. Pfizer lists three patents in the Orange Book as covering Celebrex.

66. Shortly after approval, Pfizer listed three patents in the Orange Book as covering Celebrex. These three patents encompass a broad genus of non-steroidal anti-inflammatory compounds, formulations using those compounds, and (ostensibly) methods of using those compositions. The claims of these patents include celecoxib – the active compound in Celebrex – or formulations and (ostensibly) methods of using celecoxib.

67. U.S. Patent No. 5,466,823 ("the '823 patent" or "compound patent") covers a number of compounds, including celecoxib.

68. U.S. Patent No. 5,563,165 ("the '165 patent" or "formulation" or "composition" patent) covers pharmaceutical formulations using celecoxib.

69. Both the compound and composition patents expired on November 30, 2013. The FDA gave Pfizer six more months of exclusivity because it had tested Celebrex in children. The compound and composition patents thus shielded Pfizer from competition with Celebrex until May 30, 2014.

70. This action does not raise questions about the validity or enforceability of the '823 or '165 patents. The details of those patent applications, prosecutions, and specifications, however, are relevant to the prosecution of *later* issued patents, the '068 method-of-use patent and the '048 reissue patent.

71. Pfizer later obtained a third patent that ostensibly covered methods of using the already patented celecoxib compounds and formulations to treat various conditions. U.S. Patent No. 5,760,068 ("the '068 patent" or "method-of-use patent") ostensibly covers methods of treatment, including the use of celecoxib, directed to treating acute pain and symptoms of arthritic, osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis or spondyloarthropathy, and primary dysmenorrhea or menstrual cramps.

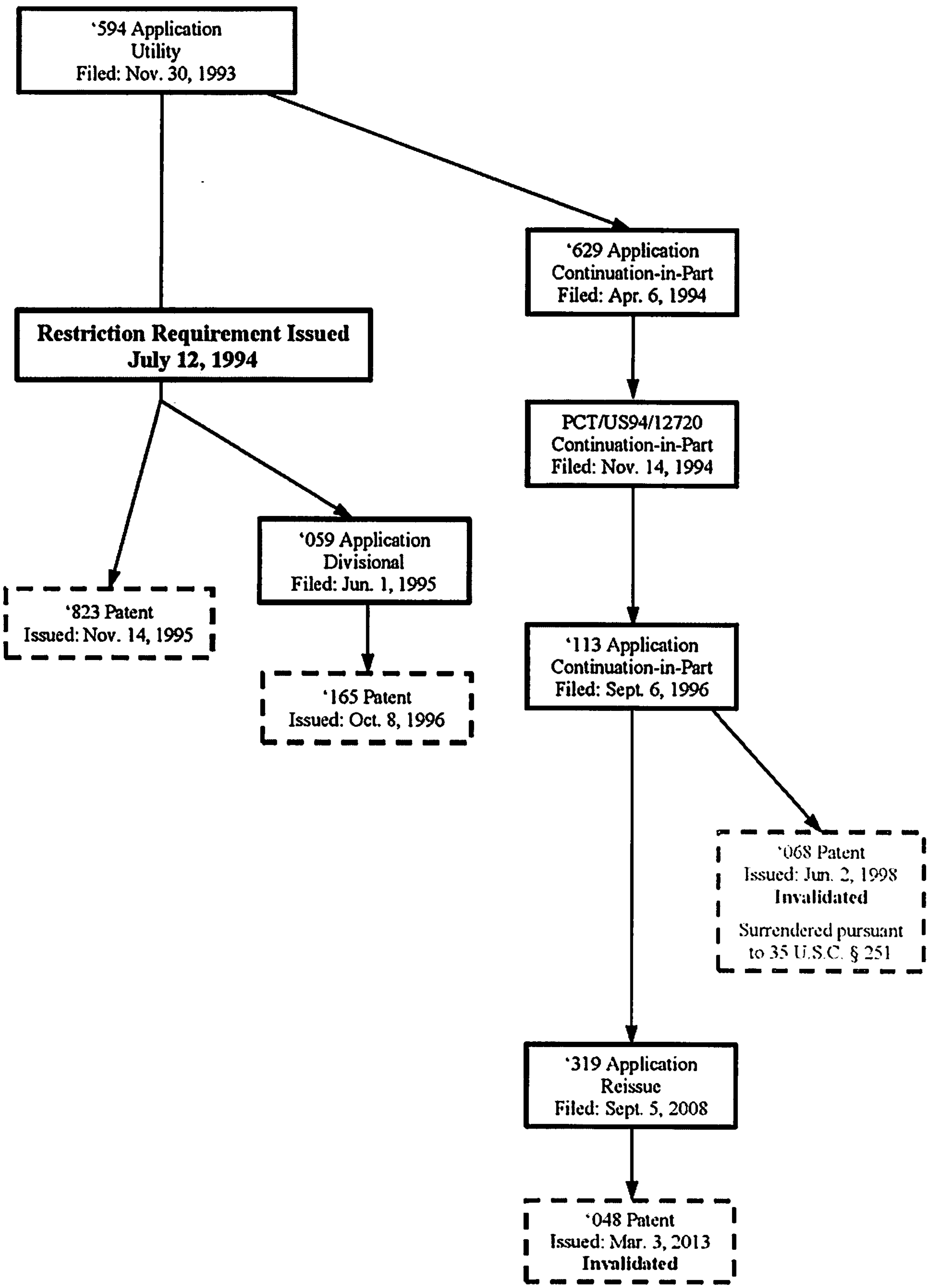
72. The method-of-use patent stemmed from a continuation-in-part application chain, and thus was scheduled to expire about a year and a half later than the other celecoxib patents, *i.e.*, it was scheduled to expire on June 2, 2015, with an extended period of exclusivity until December 2, 2015. This patent was ruled invalid in 2008.

73. After a final decision ruled the '068 patent to be invalid (because a method of using an already-patented compound cannot extend patent life by claiming methods of using the compound that were disclosed in the original compound patent), Pfizer then sought and eventually obtained and listed a fourth patent, a reissue of the original method-of-use patent. It is this reissue patent that Pfizer used for its sham litigation.

74. The patents, with issuance and expiry dates, are set forth below.

Patent No.	Issue Date	Patent Expiry	PED Expiry
5,466,823	Nov. 14, 1995	Nov. 30, 2013	May 30, 2014
5,563,165	Oct. 9, 1996	Nov. 30, 2013	May 30, 2014
5,760,068	June 2, 1998	June 2, 2015	Dec. 2, 2015
RE44,048	Mar. 5, 2013	June 2, 2015	Dec. 2, 2015

75. The patent application tree showing the applications, patent issuances and where restriction requirement were (and were not) imposed appears below. **The remainder of this page is intentionally left blank.**


'594 Application
Utility
Filed: Nov. 30, 1993
'629 Application
Continuation-in-Part
Filed: Apr. 6, 1994
Restriction Requirement Issued
July 12, 1994
PCT/US94/12720
Continuation-in-Part
Filed: Nov. 14, 1994
'059 Application
Divisional
Filed: Jun. 1, 1995
'823 Patent
Issued: Nov. 14, 1995
'113 Application
Continuation-in-Part
Filed: Sept. 6, 1996
'165 Patent
Issued: Oct. 8, 1996
'068 Patent
Issued: Jun. 2, 1998
Invalidated
Surrendered pursuant
to 35 U.S.C. § 251
'319 Application
Reissue
Filed: Sept. 5, 2008
'048 Patent
Issued: Mar. 3, 2013
Invalidated

1. The 1993-94 patent prosecution efforts led to two later applications adding new matter to the original application.

76. On November 30, 1993, Pfizer filed U.S. Patent Application No. 08/160,594 ("the '594 application"), claiming compounds, pharmaceutical formulations, and methods of use.

77. Four months later, on April 6, 1994, Pfizer filed U.S. Patent Application No. 08/223,629 ("the '629 application") as a continuation-in-part to the '594 application. The '629 application was the first in a series of continuation-in-part applications ("the '629 application chain").

78. Pfizer filed the '629 application on its own initiative, *i.e.*, it did not file the application in response to any action by the PTO. In doing so, it filed the application as a continuation-in-part of the '594 application, stating, "[t]his amendment is filed along with a Continuation-In-Part Application (filed April 6, 1994) of US Patent Application Serial No. 08/160,594 (filed November 30, 1993)." Pfizer asked the PTO to amend the patent specification to state: "This is a Continuation-In-Part application of application Serial No. 08/160,594 filed in November 30, 1993." One of Pfizer's lawyers who prosecuted the Celebrex patent applications, Philip Polster II ("Polster"), testified under oath that the '629 application was a Continuation-In-Part application.

79. The '629 application added new subject matter not found in the '594 application, and an August 1994 preliminary amendment amended ten claims and added four new claims. Because the '629 application claimed new matter, it could not have been designated as a divisional application. Pfizer's attorney, Polster, testified under oath that new matter could not be added to a divisional application.

80. The '629 application ultimately issued as U.S. Patent No. 5,521,207 ("the '207 patent"), with claims directed to a compound known as deracoxib. The deracoxib compound

was part of the new matter that was added to the '629 application. The '207 patent covers an approved animal drug product called Deramaxx Chewable Tablets.

2. Prosecution of the International PCT application.

81. On November 14, 1994, Pfizer filed International Application No. PCT/US94/12720 ("the PCT application") as a continuation-in-part of the '629 application, claiming priority to the '629 application (which itself was a continuation-in-part of the '594 application).

82. Pfizer added new matter to the PCT application. Because it added new matter, the PCT application could not have been filed as a divisional application. The PCT application was not filed as the result of a restriction requirement issued on the '629 application.

83. Pfizer ultimately obtained two other patents (not covering Celebrex) that claim priority to the PCT application and claim subject matter that was added to the PCT application.

3. The PCT application enters the U.S. national stage as the '113 application, leading to the method-of-use patent.

84. The PCT application entered the U.S. national stage as U.S. Patent Application No. 08/648,113 ("the '113 application") under 35 U.S.C. § 371(a) and was given a filing date of September 6, 1996.

85. Pfizer filed the '113 application as a continuation-in-part of the '629 application (itself a continuation-in-part of the '594 application). Pfizer added new subject matter not included in the '594 or the '629 application; among other things, it added claim 22, which was directed towards a "method for the prevention of colorectal cancer."

86. The '113 application was not filed as the result of a restriction requirement on the '629 application or the PCT application and was not intended to be a divisional application.

Because the '113 application added new matter since the '594 application, it could not have been designated as a divisional application.

87. The '113 application issued as U.S. Patent No. 5,760,068 ("the '068 patent" or "method-of-use patent"). The '068 patent had independent claims directed to methods of treating inflammation or an inflammation-associated disorder. Claims 1, 6, 9, and 11 all started, "a method of treating inflammation or an inflammation-associated disorder in a subject...."

88. The '068 patent did not contain a claim to the treatment of menstrual cramps. It did include dependent claims for treating arthritis, pain, fever, or colorectal cancer (claims 15-18).

89. The '068 patent – ostensibly claiming methods of using celecoxib to treat inflammation related disorders – was set to expire about a year and a half later than two other, earlier issued celecoxib patents. Those two other patents are now discussed.

4. Prosecution of the '059 application, leading to the formulation patent.

90. Back on July 12, 1994, the PTO had issued a restriction requirement in the '594 application, requiring Pfizer to decide whether it would pursue compounds, compositions (*i.e.*, formulations), or methods of use. The PTO stated:

> Restriction to one of the following inventions is required under 35 U.S.C. 121:
>
> I. Claims 1-20, compounds.
>
> II. Claims 21-26, compositions.
>
> III. Claims 27-37, methods of use.

91. The PTO issued the restriction requirement for the '594 application *more than three months after* Pfizer had filed the '629 CIP application. Meaning, Pfizer did not file the '629 application in response to a restriction requirement. Pfizer was not forced to – but, instead,

choose to – pursue the subject matter presented in the '629 application – including new matter – in a separate application and later applications that took priority to it.

92. On September 19, 1994, Pfizer filed an amendment and response to restriction and election requirements. Pfizer elected to prosecute its formulation claims in the '594 application.

93. The '594 application resulted in the issuance of the '823 patent, covering various compounds (including celecoxib).

94. On June 1, 1995, Pfizer filed U.S. Application No. 08/457059 ("the '059 application), claiming the pharmaceutical formulations restricted from the '594 application.

95. Pfizer filed the '059 application as a divisional application of the '594 application. A June 1, 1995 preliminary amendment stated, "this is a divisional of U.S. application 08/160,594, filed November 30, 1993."

96. In October of 1996 the '059 application issued as the '165 formulation patent. The '165 formulation patent issued a year and a half before the '068 method-of-use patent.

97. The '165 patent specification discloses methods of using celecoxib: "Compounds of Formula I would be useful for the treatment of inflammation in a subject, and for treatment of other inflammation-associated disorders...;" "The compounds are useful as anti-inflammatory agents, such as for the treatment of arthritis...;" "compounds of Formula I would be useful to treat arthritis...."

98. Claim 1 of the formulation patent refers to a "therapeutically effective amount" of certain compounds: "A pharmaceutical composition comprising a therapeutically-effective amount of a compound and a pharmaceutically-acceptable carrier or diluent, said compound selected from a family of compounds of Formula I wherein ...."

C. The Federal Circuit invalidates the '068 method-of-use patent and confirms that patent protection for Celebrex ends on May 30, 2014.

99. On or about November 11, 2003, Teva submitted the first celecoxib ANDA, ANDA No. 076898, to the FDA, seeking approval to market a generic version of Celebrex in 100 mg, 200 mg, and 400 mg strengths. Teva's ANDA contained Paragraph IV certifications to all three Celebrex patents.

100. On or about January 6, 2004, Teva notified Pfizer that Teva had filed ANDA No. 076898 containing Paragraph IV certifications to the '823, '165 and '068 patents. The Teva notice letter asserted that the claims of the '823, '165 and '068 patents were invalid, unenforceable and/or not infringed.

101. On February 19, 2004, Pfizer filed suit against Teva pursuant to Hatch-Waxman in the United States District Court for the District of New Jersey, Case No. 2:04-cv-00754-GEB-MCA, alleging that Teva's generic celecoxib product would infringe each of the three Celebrex patents ("*Teva I* litigation").

102. On March 20, 2007, following a bench trial, the United States District Court for the District of New Jersey ruled that each of the compound, formulations, and method-of-use patents were valid and infringed.[5] The court entered final judgment on April 10, 2007.

103. Teva subsequently appealed to the Federal Circuit. On March 7, 2008, the Federal Circuit affirmed the district court's finding that the '823 and '165 (the compound and composition) patents were valid and infringed by Teva's ANDA product. However, the Federal Circuit held that the '068 (method-of-use) patent was invalid, and that Pfizer was not entitled to

[5] *Pfizer Inc. v. Teva Pharms. USA, Inc.*, 482 F. Supp. 2d 390 (D.N.J. 2007) ("*Pfizer I*").

patent protection beyond May 30, 2014, the expiration of exclusivities provided by the other patents.[6]

104. In its decision, the Federal Circuit determined that the method-of-use patent was invalid for obviousness-type double patenting, meaning that the method-of-use claims in the '068 patent were not patentably distinct from the claims in Pfizer's '165 composition patent.

105. Federal law had long held that a claim to a method of using a composition is not patentably distinct if an earlier patent claimed the same composition and disclosed an identical use for it. The Federal Circuit noted that a statutory exception to this rule did not apply under the circumstances of the '068 patent. Under the exception, a patent stemming from a *divisional* application filed in response to a PTO restriction requirement will not be held to be obvious over art in the earlier, parent application. But the exception is limited to divisional applications and *not* for continuation-in-part applications.[7] Sound reasons support the clear distinction as CIP applications add additional matter and have later expiration dates. The court's invalidity decision thus turned on whether Pfizer submitted a divisional or continuation-in-part application for the method of use patent. In the case of the '068 patent, that patent stemmed from a continuation-in-part application. And so the exception did not apply. The '068 patent was declared invalid. Pfizer's *en banc* request was denied.

D. Pfizer obtains the reissued method-of-use patent by fraud.

106. To avoid the consequences of the Federal Circuit's invalidity determination, that Celebrex would become subject to competition after May 30, 2014, Pfizer committed a series of

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[6] *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 518 F.3d 1353 (Fed. Cir. 2008) ("*Pfizer II*").

[7] *Pfizer II*, 518 F.3d at 1361-62 ("If the [safe harbor provision, 35 U.S.C. §121] had included CIPs, which by definition contain new matter, the section might be read as providing the earlier priority date even as to the new matter, contrary to the usual rule that new matter is not entitled to the priority date of the original application. There was no possible reason for protecting the new matter from double patenting rejections.") (citation omitted).

fraudulent acts that caused the PTO to reissue a bogus patent as part of Pfizer's plan to prevent generic competition.

107. Federal law had long held that failure to file a divisional application cannot be corrected by reissue.[8] Similarly, an intentional act (such as filing a continuation in part application) is not the kind of mistake that can be corrected by reissue. Nevertheless, Pfizer applied for reissuance. The PTO repeatedly took the position that the failure to file a divisional application was not correctable via reissue. Pfizer (i) misdirected the PTO to address other, unrelated, errors in the patent (errors of the type that could be corrected through reissue) and (ii) misrepresented to the PTO the circumstances of its continuation-in-part applications. In reliance on these misrepresentations, the PTO granted reissuance.

1. Pfizer misrepresents the purpose of its reissue filings and misleads the PTO by falsely suggesting the '113 application was in response to a restriction requirement.

108. Following the Federal Circuit's ruling, on September 5, 2008, Pfizer filed Reissue Application Serial No. 12/205,319 ("the reissue application"). Pfizer asked the PTO to reissue the '068 patent in order to "correct" the "error" that the '113 application had been filed as a CIP application rather than a divisional one. The reissue application also suggested the '113 application had originally been filed in response to the restriction requirement. These statements were all false.

109. In a September 5, 2008 Preliminary Amendment filed with the reissue application, Scott A. Williams ("Williams"), in his capacity as attorney for Pfizer, stated that Pfizer was amending the claims and specification "so that the '113 Application from which the

[8] *See, e.g., In re Watkinson*, 900 F.2d.230, 231 (Fed. Cir. 1990).

'068 Patent issued qualifies as divisional application in compliance with the recent Federal Circuit opinion."

110. In a May 27, 2010 Reply to Office Action, Polster, in his capacity as attorney for Pfizer, stated, "Applicants request correction of an error in the specification of the original patent resulting in it being denominated a continuation-in-part instead of a divisional, and deletion of unnecessary portions of the specifications and claims."

111. An "error" under Section 251 requires an error in the patent and an error in conduct. However, the preliminary amendment filed with the reissue application did not identify an error in patent or an error in conduct with respect to the '113 application. Instead, Pfizer's purported correction of an error was "ultimately no more than a statement of a now-regretted choice, because the [Pfizer] identif[ed] no cognizable false or deficient understanding of fact or law that underlay the choice. This is not 'error' as required by section 251."[9]

112. The alleged error identified by Pfizer in the preliminary amendment was a misrepresentation made to the PTO with a specific intent to deceive the PTO.

113. In the May 27, 2010 Reply to Office Action, Polster, in his capacity as attorney for Pfizer, further stated, "The Applicants did timely file the '113 Application but failed to properly denominate it as a divisional application by satisfying the requirements set forth in the subsequent *Pfizer v. Teva* decision."

114. This was completely untrue. The '113 application was in fact "properly denominated" at the time it was filed, and the proper denomination was as it was, a *continuation-in-part* application. And there was nothing in the Federal Circuit's *Teva I* decision that even insinuated a need to have Pfizer go back to "correct" its intentional patent prosecutorial

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[9] *In re Dinsmore*, slip op. at 8.

decisions. There was no error in the specification of the original patent resulting in it being denominated a continuation-in-part instead of a divisional; the specification of the '068 patent disclosed the correct claims of priority as strategically chosen and intended by Pfizer.

115. In the May 27, 2010 Reply to Office Action, Polster, in his capacity as attorney for Pfizer, also stated:

> Further, to deny the protection under 35 U.S.C. § 121 to Applicants solely because the Federal Circuit held that Applicants did not file a proper divisional application, when Applicants are trying to correct that defect through the present reissue proceeding by conforming their application---which was timely filed---to the proper divisional application form precisely because of the Federal Circuit holding, results in a circular trap that belies the whole purpose of the reissue statute. Applicants acknowledge that the application that issued as the '068 Patent in 1998 does not comply with the definition of a divisional application entitled to protection under 35 U.S.C. § 121 as enunciated by the Federal Circuit ten years later in *Pfizer v. Teva*. The correction of that defective application to a proper divisional application form is exactly the 'error' that Applicants are appropriately attempting to correct through the reissue process.[10]

116. Pfizer did not denominate the '113 application as a divisional; at the time Pfizer did not have a basis in law or fact to make it a divisional, had elected voluntarily to add subject matter to the disclosure, and the '113 application's priority document, the '629 application, was itself filed as a CIP of the '594 application months before any restriction requirement. It was false and deceptive for Pfizer to mislead the TPO to believe that the '113 application was in response to a restriction requirement when, in fact, it was not.

117. The examiner responded by telling Pfizer what Federal Circuit case law already said quite clearly - that failure to file a divisional application is not correctable through reissue:

> The reissue oath/declaration filed with this Application was found defective because the error which is relied upon to support the

[10] Attorney Philip B. Polster II, in his capacity as attorney for Pfizer.

> reissue Application is not an error upon which a reiusse can be based. *See* MPEP 1412.02. The oath/declaration fails to specifically identify an error. Failure to 'timely' file a divisional application prior to issuance of the original patent is not correctable in reissue under 35 U.S.C. 251.

118. Pfizer, through A. Dean Olson ("Olson") in his capacity as attorney for Pfizer, requested continued examination in a Response Accompanying RCE dated March 29, 2011, stating "The identification of this application as a divisional application rather than as a continuation-in-part application now is not only proper, but is *required to correctly describe the relationship between the two applications*" (emphasis added). Pfizer knew at the time it made this statement that there was no restriction requirement during the prosecution of the '068 patent application chain, and that none of the applications in the '068 patent application chain was properly a divisional application for the purpose of 35 U.S.C. §121 since none of these applications were filed in response to a restriction requirement.

119. In a December 29, 2011 Office Action, the patent examiner issued a non-final rejection and stated: "The reissue oath/declaration filed with this application is defective because the error which is relied upon to support the reissue application is not an error upon which a reissue can be based. *See* 37 CFR 1.175(a)(1) and MPEP § 1414." The examiner further maintained that the claims "were already found to be unpatentable by United States Court of Appeals for the Federal Circuit in a [sic] March 07, 2008."

120. Once again, Pfizer sought to mislead the PTO by suggesting it had simply made "errors" in the denomination of the '113 application. But Pfizer had intentionally and purposefully filed the '113 application as a CIP, and its assertion that the '113 application was filed erroneously as a CIP rather than a divisional was a misrepresentation made to the PTO with a specific intent to deceive the PTO. Pfizer's sole reason for the alleged "correction" of the so-

called "error" was to remove the '165 patent as a double-patenting prior art reference; to undo an intentional act that had originally sought to garner longer, unlawful patent protection.

121. In the June 6, 2012 Response, Olson, in his capacity as attorney for Pfizer, stated that "prior to the CAFC decision, Applicants could not have reissued their patent based on what was later determined to be erroneous (the filing of a C-I-P) because the district court held there was no double-patenting." This mischaracterized the district court's opinion in the *Teva I* litigation.[11]

122. Pfizer misrepresented to the PTO during the reissue proceedings that it committed an "error" by filing a CIP instead of a divisional during the prosecution of the '068 patent, and this "error" led to the invalidation of claims of the '068 patent by the Federal Circuit because a CIP does not fall within the "safe harbor" of 35 U.S.C. § 121.

123. Because there was no restriction requirement during the prosecution of the '068 patent application chain, Applicants could not have filed a divisional application that complied with the "safe harbor" provision of 35 U.S.C. § 121.

124. During the prosecution of the '048 patent, Pfizer consistently and systematically concealed the fact that it could not have filed a divisional application that complied with the "safe harbor" provision of 35 U.S.C. § 121 in the '068 patent Application Chain. Even if Pfizer had filed a divisional application instead of the CIP application it actually filed, because no restriction requirement had been made as of that filing date, such hypothetical divisional would have been a voluntary divisional and, as such, would not have been protected by the "safe harbor" provision of 35 U.S.C. § 121.

[11] *Pfizer I*, 482 F. Supp. 2d at 475-476.

125. Pfizer's misrepresentations to the PTO during the reissue proceedings were made to the PTO with the specific intent of deceiving the PTO.

126. Pfizer's misrepresentations to the PTO during the reissue proceedings were material to the PTO and directly resulted in the issuance of the '048 patent.

127. Had the patent examiner reviewing the reissue application known that a restriction requirement did not take place during the '068 patent application chain, the examiner would not have allowed the '048 reissue patent to issue.

128. The '068 patent was purposefully filed as a continuation-in-part application, rather than as a continuation application or as a divisional application, because at the time the CIP application was filed, Pfizer had made additional compounds for which it wanted patent protection and the surest way, if not the only way, of getting such patent coverage was to include them in the CIP application. This strategy was successful in that it resulted in multiple U.S. and foreign patents being issued with claims to the added subject matter, all to Pfizer's benefit.

129. Pfizer's belated designation of the '048 patent as a divisional of the '594 application was done for the purpose of removing the '165 patent as a double-patenting prior art reference, not because it was required to correctly describe the relationship between the two applications.

2. Pfizer makes further false misrepresentations and deliberately omits facts during the reissue proceedings.

130. Pfizer, including the applicants for the '048 patent, their attorneys, agents, and others substantively involved in the prosecution of the application for the '048 patent, engaged in a pattern or inequitable conduct during the prosecution of the application. Pfizer intentionally misrepresented the facts surrounding the prosecution history of related patents, including (a) claiming that the filing of the '629 application as a continuation-in-part was an "error" and that

that application was filed in response to a restriction requirement; (b) averring that claims previously asserted against Teva are indefinite, (c) misrepresenting the true basis for the reissue request, (d) misrepresenting to the PTO that the reissue application did not comprise new matter, and (e) failing to list the correct inventors.

a. Pfizer intentionally misrepresented facts surrounding the alleged restriction requirement to gain issuance of the '048 patent.

131. The invalid '068 method-of-use patent issued as a result of the following patent application chain: the '594 application; the '629 application (filed as a continuation-in-part application of the '594 application); the PCT application (claiming priority to the '629 application); and the '113 application (the national stage entry for the PCT application and a continuation-in-part of the '629 application).

132. Pfizer filed the '594 application on November 30, 1993. Pfizer filed the '629 application (which eventually resulted in the '068 patent) on April 6, 1994 as a continuation-in-part of the '594 application. Pfizer filed the '629 application as a continuation-in-part application, and did not intend for it to be a divisional application.

133. At the time Pfizer filed the '629 application, the PTO had *not* issued any restriction requirement during the prosecution of the '594 application. It was only later, three months *after* Pfizer filed the '629 application, that the PTO required Pfizer to restrict the subject matter pursued in the '594 application.

134. In Pfizer's September 5, 2008 Preliminary Amendment, Williams, in his capacity as attorney for Pfizer, deceptively quoted language from the Federal Circuit's decision that implied the '629 application was filed in response to a restriction requirement:

> During the examination of the United States Application Serial No. 08/160,594 (the "'594 application"), filed on November 30, 1993, which issued as United States Patent No. 5,466,823 (the "'823 Patent"), the Examiner issued a three-way restriction requirement

> described further below among various compounds, pharmaceutical compositions and methods of use. The United States Court of Appeals for the Federal Circuit in a March 7, 2008 opinion, *Pfizer Inc. v. Teva Pharmaceuticals USA Inc.*, 86 U.S.P.Q.2d 1001 (Fed. Cir. 2008), determined that the application from which U.S. Patent No. 5,760,068 issued failed to qualify as a divisional application entitled to protection under 35 U.S.C. § 121. As a result, the Federal Circuit further held that claims 1-4 and 11-17 of the patent were invalid for obviousness-type double patenting based on the issued claims of a related family member, U.S. Patent No. 5,563,165. Applicant therefore is requesting reissue of U.S. Patent No. 5,760,068 to correct those errors that prevented the application from which the patent issued from complying with the definition of a divisional application pursuant to M.P.E.P. 201.06 entitled to protection under 35 U.S.C. § 121 as recently enunciated by the Federal Circuit.

135. Later in the preliminary amendment, Williams quoted the following portion of the Federal Circuit decision concerning the restriction requirement:

> Subsequent to the restriction requirement but before the '594 application issued, Pfizer filed a series of continuation applications claiming priority to the '594 application and covering the non-elected subject matter which it had elected not to prosecute in the original '594 application. In particular, Pfizer filed a divisional application, which ultimately issued as the '165 patent, that included the restricted-out composition claims, and a continuation-in-part application ("CIP"), which ultimately issued as the '068 patent, that included the restricted-out method claims.

136. The Federal Circuit's summary – strategically quoted by Pfizer – is inaccurate. The Federal Circuit seems to have assumed that the '113 application issued as a result of a restriction requirement. But, as described above, the restriction requirement issued for the '594 application came *after* Pfizer filed the '113 application.

137. Pfizer knew when it filed the preliminary amendment that the application that issued as the '068 patent was not filed as the result of a restriction requirement. Pfizer knowingly and intentionally included the Federal Circuit's inaccurate summary of the prosecution of the '068 patent application chain with the specific intent to deceive the PTO.

138. The fact that no restriction requirement was issued during the prosecution of the '068 patent application chain would have been material to the examiner of the reissue patent.

b. Pfizer intentionally misrepresented the actual basis for the reissue application.

139. In its March 9, 2011 Response Accompanying RCE, Pfizer listed various errors in the claims of the '068 patent that purportedly rendered the claims indefinite or improper dependent claims.

140. Prior to March 9, 2011, Pfizer had not raised any concerns about the claims of the '068 patent, and Pfizer had asserted infringement of claims 1-4 and 11-17 in the *Teva I* litigation.

141. Pursuant to Rule 11 of the Federal Rules of Civil Procedure, Pfizer represented that the claims of the '068 patent were valid and infringed when it asserted them in the *Teva I* litigation.

142. Pfizer's sole basis for raising these purported errors on March 9, 2011 was to present purportedly correctable errors to the PTO to overcome the final rejection of the reissue application and to disguise its true motivation for seeking reissue of the invalidated '068 patent.

143. Rather than correct these purported errors listed in the March 9, 2011 Response Accompanying RCE, Pfizer simply cancelled the claims of the '068 patent (specifically, claims 2-12) and drafted new claims with the benefit of over ten years of hindsight and knowledge concerning the commercial embodiment of the '068 patent.

144. Pfizer's misrepresentations to the PTO during the prosecution of the reissue application were made to the PTO with the specific intent of deceiving the PTO.

145. Pfizer's misrepresentations to the PTO during the prosecution of the reissue application were material to the PTO and directly resulted in the issuance of the '048 patent.

c. Pfizer intentionally broadened the scope of the claims through reissue.

146. In the May 27, 2010 Reply to Office Action, Polster, in his capacity as attorney for Pfizer, stated "the presently claimed subject matter also is claimed in the '068 Patent."

147. Pfizer was aware when it filed this Reply that the '068 patent did not claim a method of treating menstrual cramps.

148. 35 U.S.C. § 251 states in relevant part:

> (d) No reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent.

149. Pfizer was aware that by including a claim directed to a method of treating menstrual cramps, it was improperly broadening the scope of the claims of the '068 patent.

150. Pfizer intentionally misrepresented the scope of the '068 patent to the PTO.

151. Pfizer's misrepresentations to the PTO during the prosecution of the reissue application were made to the PTO with the specific intent of deceiving the PTO.

152. Pfizer's misrepresentations to the PTO during the prosecution of the reissue application were material to the PTO and directly resulted in the issuance of the '048 patent.

d. Pfizer intentionally misrepresented that the reissue application did not contain new matter.

153. In the September 5, 2008 Preliminary Amendment, Williams, in his capacity as attorney for Pfizer, stated that the preliminary amendment filed with the reissue application "[a]mends the specification of the '068 Patent to delete portions not in the priority application (the '594 Application)" and that "[n]o new matter has been introduced as a result of these amendments."

154. In the March 9, 2011 Response Accompanying RCE, Olson, in his capacity as attorney for Pfizer, stated that the reissue application "does not add any new matter by

amendment." Olson, in his capacity as attorney for Pfizer, repeated the same statement in the July 19, 2011 Statement of Substance of the Interview, Amendment and Supplemental Response.

155. Pfizer was aware when it made these statements to the PTO that the reissue application included material that was not in the alleged priority application.

156. Pfizer intentionally and knowingly added new matter to the reissue application, including but not limited to Examples 153-156 and 160 in Table VII.

157. Pfizer intentionally misrepresented to the PTO that the reissue application did not contain new matter.

158. Pfizer's misrepresentations to the PTO during the prosecution of the reissue application were made to the PTO with the specific intent of deceiving the PTO.

159. Pfizer's misrepresentations to the PTO during the prosecution of the reissue application were material to the PTO and directly resulted in the issuance of the '048 patent.

e. Pfizer intentionally concealed the identity of an inventor.

160. Dr. Daniel Simmons, a professor at Brigham Young University ("BYU"), discovered COX-2, an inducible form of cyclooxygenase.

161. Beginning in 1991, Dr. Simmons and BYU entered into a collaboration with Monsanto (the corporate predecessor of Pharmacia, Inc., a wholly-owned subsidiary of Pfizer) to develop a non-steroidal anti-inflammatory drug ("NSAID") which would selectively inhibit COX-2.

162. As part of the collaboration with Monsanto, on April 29, 1991, Dr. Simmons provided to Monsanto, on a confidential basis, his murine (mouse) COX-1 and COX-2 clones and COX-2 antibodies.

163. Dr. Simmons and BYU had not made these materials public prior to their disclosure to Monsanto.

164. Prior to the collaboration with Dr. Simmons, Monsanto did not have access to the necessary tools for screening compounds which were COX-2 selective inhibitors because Monsanto's program was premised on the existence of a single cyclooxygenase target.

165. Monsanto had been working to develop steroid-like (as opposed to nonsteroidal) inhibitors of cyclooxygenases prior to gaining access to Dr. Simmons' confidential material.

166. Monsanto accepted and immediately began using the materials provided by Dr. Simmons.

167. Dr. Simmons made inventive contributions to the alleged invention claimed in the '068 patent.

168. Pfizer's conception of celecoxib, the compound that is the subject matter of the '068 patent, was only possible using the inventive contribution of Dr. Simmons.

169. Dr. Simmons provided Pfizer with the essential means to identify the claimed celecoxib compound, including COX-1 and COX-2 clones and instructions for using such clones for the testing of NSAIDs.

170. Monsanto's only source of murine COX-1 was Dr. Simmons and Brigham Young University and the only possible sources of murine COX-2 were Dr. Simmons (April 29, 1991) and Dr. Harvey Herschman of UCLA (August 24, 1992).

171. Monsanto had tested the COX-2 clones provided by Dr. Harvey Herschman without success.

172. Pfizer was aware of the key role played by the materials and information provided by Dr. Simmons in the conception of the invention claimed in the '823, '165 and '068 patents.

173. Dr. Simmons contributed to the conception of the invention of every claim of the '068 patent because all claims are directed to methods of use of the compound celecoxib, which

is a COX-2 selective inhibitor, and which at a minimum was identified on the basis of the materials and information provided by Dr. Simmons.

174. Pfizer engaged in knowing concealment of material information by failing to disclose the collaboration between Dr. Simmons and Monsanto during the prosecution of the '068 patent.

175. Pfizer intentionally concealed Dr. Simmons' substantial and inventive contribution to the conception of the celecoxib compound and its claimed methods of use.

176. Pfizer knowingly filed false affidavits during the prosecution of both the '068 and '048 patents concerning the inventors of the subject matter of the patents.

177. On October 18, 2006, BYU and Dr. Simmons filed suit against Pfizer in the United States District Court for the District of Utah, Central Division, Case No. 2:06-cv-00890-TS, asserting several causes of action including a correction of inventorship of the '823, '165, and '068 patents under 35 U.S.C. § 256 ("BYU Litigation").

178. On November 14, 2011, Pfizer filed a motion for summary judgment in the BYU Litigation on plaintiffs' claim for correction of inventorship.

179. On March 22, 2012, the district court denied Pfizer's motion, finding that BYU had "put forward evidence (1) that Simmons discovered COX-2 and conceived of a method for determining whether a compound was COX-2 selective; (2) that Simmons's contribution was greater than the exercise of ordinary skill; and (3) that Pfizer used Simmons's method in developing its own COX-2 inhibitor." The court further held that it was reasonable to infer that the inventors of the patents "built off Simmons's work."

180. On April 28, 2012, just over one month after the court denied Pfizer's motion for summary judgment on the inventorship issue, the parties purportedly settled the BYU litigation for $450 million dollars.

181. As part of that settlement, Dr. Simmons assigned and transferred to Pfizer his rights to the disputed patents.

182. Pfizer intentionally provided tens of thousands of pages of irrelevant material from the BYU litigation to the PTO in an attempt to bury relevant and material information relating to Dr. Simmons' substantial and inventive contribution to the conception of the celecoxib compound and its claimed methods of use.

183. Pfizer intentionally concealed that the settlement in the BYU litigation included an assignment of Dr. Simmons' rights and interests in the '068 patent to Pfizer.

184. Pfizer's failure to disclose the correct inventorship to the PTO during the prosecution of the reissue application constituted the withholding of information material to the patentability of the claims that issued as the '048 patent.

185. Pfizer's withholding of this information was deliberate and done with a specific intent to deceive the PTO, and constitutes a violation of the duties of disclosure and/or candor under 37 C.F.R. § 1.56.

186. The facts concerning the true inventorship associated with the '048 patent were material to patentability of the claims such that the PTO would not have issued the claims of the '048 patent had this information been disclosed during the prosecution of the reissue application.

E. Pfizer lists the reissue patent in the Orange Book and files baseless litigation against its would-be generic competitors.

187. On March 5, 2013, the reissue application issued as the '048 patent. On the same day the '048 patent issued, Pfizer requested that the FDA list the '048 patent in the Orange Book.

The '048 patent was listed in the Orange Book on March 7, 2013. Pfizer thus represented under oath that the '048 patent was reasonably enforceable. That was false.

188. Generic companies had been lining up for years to launch generic celecoxib products. In addition to Teva, at least four additional generic manufacturers submitted ANDAs to the FDA seeking approval to market generic celecoxib capsules:

Applicant	ANDA	Date Submitted	Tentatively Approved
Teva	076898	Nov. 13, 2003	Apr. 27, 2012
Mylan Pharmaceuticals, Inc. ("Mylan")	078857	Mar. 2, 2007	Apr. 29, 2011
Watson Laboratories, Inc. ("Watson")	200562	Oct. 23, 2009	Sept. 21, 2012
Lupin Pharmaceuticals, Inc. ("Lupin")	202240	by Dec. 30, 2010	none reported
Apotex Inc. / Apotex Corp. ("Apotex")	204197	by July 12, 2012	none reported

189. Before the '048 patent was reissued, three ANDAs for generic celecoxib capsules had received tentative approval from the FDA: ANDA No. 076898, submitted by defendant Teva; ANDA No. 078857, submitted by Mylan; and ANDA No. 200562, submitted by defendant Watson. Those ANDAs would have been eligible for final FDA approval on May 30, 2014 (*i.e.*, upon expiration of the pediatric exclusivity associated with the '823 and '165 patents); absent Pfizer's conduct in procuring and enforcing the '048 reissue patent all of these ANDAs would have received final FDA approval by May 30, 2014.

190. On March 5, 2013, the same day that the PTO issued the '048 patent, Pfizer filed suit against the five ANDA sponsors listed above — Teva, Mylan, Watson, Lupin and Apotex — in the United States District Court for the Eastern District of Virginia, Case No. 2:13-cv-00121-AWA-LRL (the "*Teva II* action"), alleging that each of the ANDA sponsors' generic Celebrex products would infringe the '048 reissue patent.

191. The *Teva II* action was a sham. No reasonable litigant would realistically expect Pfizer to succeed on the merits of any of the infringement claims against Teva, Mylan, Watson, Lupin or Apotex because the '048 reissue patent was manifestly invalid.

192. The Federal Circuit had already ruled that validating the kind of method-of-use claims sought in these circumstances for celecoxib would be shocking, and it quoted a long held principle:

> It would shock one's sense of justice if an inventor could receive a patent upon a composition of matter, setting out at length in the specification the useful purposes of such composition, manufacture and sell it to the public, and then prevent the public from making any beneficial use of such product by securing patents upon each of the uses to which it may be adapted.[12]

193. Any reasonable litigant would expect a district court to follow accepted law. Accepted law long held that the reissue process is not available to "correct" the failure to file a divisional application. Accepted law also long held that the reissue process is not available to "correct" intentional acts. There was no factual issue that (i) the '113 application had been filed as a continuation-in-part application, and (ii) that Pfizer's doing so was entirely intentional. Pfizer had intentionally sought and received the benefits of a CIP application; it could not later seek to undo those intentional acts through the reissue process.

194. Pfizer filed the Teva II for the purpose of frustrating lawful competition and not for any valid, lawful purpose. Pfizer's intent was to file the sham suit and use it as a platform to prolong market exclusivity longer than that to which it was lawfully entitled.

195. On November 22, 2013, Mylan, Watson, Lupin and Apotex moved for summary judgment against Pfizer, asserting that the '048 patent was invalid. Teva did not move for summary judgment against Pfizer.

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[12] *Pfizer II*, 518 F.3d at 1363 (quoting *Geneva Pharms., Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1386 (Fed. Cir. 2003)).

F. The District Court invalidates the reissued patent.

196. On March 12, 2014, the United States District Court for the Eastern District of Virginia ruled that the '048 patent is invalid. The district court held that

> the '048 patent is invalid under 35 U.S.C. § 251 because, even if other errors supported the reissue application under § 251, the failure to file a divisional is not an error correctable under 35 U.S.C. § 251, and is not a narrowing change to the patent's claims. Additionally, because the applicant intentionally filed a CIP application as opposed to a divisional, and intentional acts are not correctable via reissue, the '048 patent violates § 251 of the reissue statute as a matter of law and is invalid.

197. The district court also held that the claims of the '048 patent are not patentably distinct from the claims of the '165 patent, and that as a result, the '048 patent is invalid on the basis of obviousness-type double patenting.

198. Although the district court had acted with dispatch in ruling on the invalid '048 reissue patent, Pfizer used its sham suit as a platform to "settle" its sham claims with the would-be generic entrants and thereby prolong exclusivity beyond May 30, 2014.

G. Pfizer settles with Teva and Watson.

199. On April 17, 2014, after the district court granted summary judgment but before the district court entered a final judgment, Teva announced that it had entered into a settlement agreement with Pfizer to settle the Teva claims in *Teva II.* According to Teva, "[u]nder the terms of the settlement, Teva may launch its generic versions in December 2014, or earlier under certain circumstances." The terms of the settlement agreement between Pfizer and Teva have not otherwise been publicly disclosed.

200. One week later, on April 24, 2014, Watson announced that it, too, had entered into a settlement agreement with Pfizer to settle its issues in the patent litigation. According to Watson, "[u]nder the terms of the agreement, Pfizer will grant [Watson] a license to market its

generic Celebrex® beginning in December 2014, or earlier under certain circumstances. Other details of the settlement were not disclosed." Pfizer subsequently confirmed its settlement agreements with Teva and Watson, stating that it "has entered into settlement agreements with certain . . . generic drug companies granting them licenses to launch their generic versions of celecoxib in the U.S. beginning in December 2014, or earlier under certain circumstances. Under certain conditions, the licenses may be royalty-bearing through the remaining term of the reissue patent."

H. The District Court for the Northern District of West Virginia upholds the FDA's determination that Teva is entitled to 180-day exclusivity as the first ANDA filer.

201. On April 24, 2014, the FDA sent a letter addressed to "Dear Celecoxib ANDA Applicant" that provided the FDA's position on the eligibility of ANDA applicants for 180-day exclusivity under the pre-MMA version of the FDCA in a situation involving a reissued patent. The FDA concluded that

> for purposes of 180-day exclusivity, upon the listing of a reissued patent, a prior court decision on the original patent is not regarded as having triggered 180-day exclusivity for the single bundle of patent rights represented by the original and reissued patent. In such a case, eligibility for 180-day exclusivity is only available to the applicant that first filed a paragraph IV certification to the original patent, and that applicant must make a timely submission of a paragraph IV certification to the reissued patent to remain eligible for 180-day exclusivity.

202. While the FDA noted in its April 24 letter that it was "not making a determination with respect to 180-day exclusivity in a particular case," the practical result of the FDA's stated position on eligibility for exclusivity in situations involving a reissued patent was that Teva, and only Teva, would be eligible for 180-day exclusivity with respect to generic celecoxib capsules in 100 mg, 200 mg and 400 mg strengths.

203. On April 25, 2014, Mylan filed suit against the FDA in the United States District Court for the Northern District of West Virginia, Case No. 1:14-cv-00075-IMK, challenging the FDA's April 24 decision regarding exclusivity. Mylan sought a preliminary injunction enjoining the FDA from withholding final approval to any celecoxib ANDA applicant that submitted a Paragraph IV certification to the '048 patent on March 7, 2013 (the day the '048 patent was listed in the Orange Book) and compelling the FDA to grant final approval to Mylan's celecoxib ANDA on May 30, 2014.

204. On May 29, 2014, the District Court for the Northern District of West Virginia denied Mylan's motion for a preliminary injunction. The district court found that "the FDA's decision to treat an original and its reissued patent as having a single bundle of rights is reasonable and allows the agency to administer the Hatch-Waxman Act in a predictable manner."

I. The FDA gives Teva's celecoxib ANDA final approval.

205. Also on May 30, 2014, the FDA granted Teva final ANDA approval, stating that Teva "received approval to market celecoxib capsules in 50 milligram, 100 mg, 200 mg, and 400 mg strengths, and has 180-day exclusivity on the 100 mg, 200 mg, and 400 mg strength products." Even though Teva now has *final* FDA approval to market its celecoxib product, Teva has not launched a generic product. Why? Because Pfizer's scheme has worked. Pfizer procured the '048 reissue patent by fraud and trickery, filed the reissue patent in the Orange Book knowing it could not be reasonably enforced against generics, filed the sham *Teva II* lawsuit against Teva, and then used that sham lawsuit to negotiate a delayed entry date out of Teva. As a result, Teva will not be launching generic celecoxib until the end of 2014.

J. Pfizer settles with Mylan.

206. On June 2, 2014, Mylan announced that it had entered into a settlement agreement with Pfizer to settle the Celebrex patent litigation. According to Mylan, "[u]nder the terms of the

agreement, Mylan will begin selling product at the earliest market formation, however in any case not later than December 2014. All other terms and conditions of the settlement and license agreement are confidential. . . . Additionally, Mylan has appealed the decision by the United States District Court for the Northern District of West Virginia denying Mylan's request for an injunction in its suit against the FDA. Mylan continues to believe that FDA seriously erred in its decision awarding one party eligibility for 180 days of exclusivity on Celecoxib, and will continue with this suit independent of the aforementioned settlement."

VI. MONOPOLY POWER AND MARKET DEFINITION

207. At all relevant times, Pfizer had monopoly power in the market for celecoxib capsules, *i.e.*, Celebrex and its AB-rated generic equivalents, because it had the power to maintain the price of the drug it sold as Celebrex at supracompetitive levels without losing substantial sales to other products prescribed and/or used for the same purposes as Celebrex, with the exception of AB-rated generic celecoxib capsules.

208. NSAIDs are a group of drugs used to temporarily relieve pain and inflammation. They work by blocking the production of prostaglandins, or chemicals believed to be associated with pain and inflammation.

209. Some NSAIDs act by blocking the action of two different enzymes, Cyclooxygenase-1 and Cyclooxygenase-2 (COX-1 and COX-2), which the body uses to make prostaglandins. These NSAIDs, such as ibuprofen and naproxen, are known as "nonselective" NSAIDs.

210. While the use of a nonselective NSAID may reduce pain and inflammation, they may also result in serious gastrointestinal bleeding, heart attacks, and strokes. The gastrointestinal bleeding problems have been traced specifically to the blocking of COX-1. Some of the prostaglandins produced by the COX-1 enzyme help protect the lining of the

stomach from acid, so blocking this enzyme increases the risk of stomach upset, stomach bleeding and ulcers.

211. Selective COX-2 inhibitors are a newer type of NSAID that primarily block the COX-2 enzyme, and not the COX-1 enzyme. The theory with selective COX-2 inhibitors is that they might provide similar relief from pain and inflammation-related disorders than non-selective ones, but with less gastrointestinal side effects.

212. Over the years, the FDA has only approved three selective COX-2 inhibitors: rofecoxib, sold under the name Vioxx; valdecoxib, sold under the name Bextra; and celecoxib, sold under the name Celebrex. Vioxx was withdrawn from the market in 2004 because it was linked to an increased risk of heart attacks and strokes. Bextra was withdrawn in 2005 because it was associated with an increased risk of serious cardiovascular problems in people who had undergone coronary artery bypass graft surgery as well as a higher risk of life-threatening skin reactions than other NSAIDs. For many years Celebrex has been the only selective COX-2 inhibitor on the market in the United States.

213. Pfizer differentiates Celebrex from other medications used to treat the indications for which it is approved, *i.e.*, osteoarthritis, rheumatoid arthritis, juvenile rheumatoid arthritis, ankylosing spondylitis, acute pain, and primary dysmenorrhea. Among other things, over the years Pfizer has differentiated Celebrex from other drugs based on its reports of the results of clinical studies that indicate that a lower percentage of patients taking Celebrex report stomach discomfort (including indigestion, abdominal pain, and nausea) versus those taking prescription ibuprofen and naproxen.

214. It has become generally accepted by many that celecoxib has shown an advantage in lowering the risk of serious ulcer complications in the short-term (six months or less)

compared with other NSAIDs. Studies also indicate that Celebrex is effective at reducing the risk of ulcers with longer-term use.

215. Manufacturers attempt to differentiate brand name drugs like Celebrex based on features and benefits (including safety and efficacy), and not based on price. Doctors and patients are generally price-insensitive when prescribing and taking prescription drugs like Celebrex. This is due in part to the presence of insurance that bears much of the cost of prescriptions and other institutional features of the pharmaceutical marketplace. Different patients may respond differently to different drugs and even drugs within the same therapeutic class as Celebrex do not constrain the pricing of Celebrex.

216. A small but significant, non-transitory price increase by Pfizer for Celebrex would not have caused a significant loss of sales to other products prescribed and/or used for the same purposes as Celebrex, with the exception of generic celecoxib capsules.

217. Less expensive generic versions of other NSAIDs are available (including Relafen (nabumeton)) but those less expensive products do not exhibit cross price elasticity with and therefore do not constrain the price of Celebrex.

218. Pfizer needed to control only Celebrex and its AB-rated generic equivalents, and no other products, in order to maintain the price of Celebrex profitably at supracompetitive prices while preserving all or virtually all of its sales. Only the market entry of a competing, AB-rated generic version of Celebrex would render Pfizer unable to profitably maintain its current prices of Celebrex without losing substantial sales.

219. Celebrex also sold Celebrex at prices well in excess of marginal costs, and substantially in excess of the competitive price, and enjoyed high profit margins.

220. Pfizer has had, and exercised, the power to exclude and restrict competition to Celebrex and AB-rated bioequivalents.

221. Pfizer, at all relevant times, enjoyed high barriers to entry with respect to competition in the relevant product market of celecoxib capsules due, in large part, to legally and illegally created patent protections, legally and illegally created regulatory bars to FDA approval of AB-rated generic competitors, and high costs of entry and expansion.

222. To the extent the Plaintiff is legally required to prove monopoly power through circumstantial evidence by first defining a relevant product market, the Plaintiff alleges that the relevant market is all celecoxib capsules (*i.e.*, Celebrex in all its dosage strengths, and its AB-rated generic equivalents). During the period relevant to this case, Pfizer has been able to profitably maintain the price of celecoxib capsules well above competitive levels.

223. The relevant geographic market is the United States and its territories.

224. At all relevant times, Pfizer's market share in the relevant market was and remains 100%.

VII. MARKET EFFECTS AND DAMAGES TO THE CLASS

225. But for the anticompetitive conduct alleged above, multiple generic manufacturers would have entered the market with their generic celecoxib products as early as May 31, 2014, when the pediatric exclusivities associated with the '823 and '165 patents expired. Instead, Pfizer willfully and unlawfully maintained its monopoly power in the market for celecoxib through a scheme to exclude competition. The scheme forestalled generic competition and carried out its anticompetitive effect of maintaining supra-competitive prices for Celebrex. Pfizer implemented its scheme by fraudulently obtaining the '048 reissue patent, prosecuting a sham patent infringement lawsuit against the generic manufacturers, and abusing the Hatch-Waxman framework. These acts, in combination and individually, were anticompetitive.

226. If Pfizer had not defrauded the PTO, (i) the '048 reissue patent would never have been issued, (ii) it could never have been used as a vehicle to bring suits against would-be makers of generic celecoxib products, and (iii) those makers would have been able to launch generic celecoxib by May 31, 2014. Moreover, if the '048 reissue patent had not issued, then Teva would not have had a basis by which to argue that it was entitled to resurrect its first-to-file status for celecoxib (because the sole basis by which it has been able to do so is that the PTO's reissuance of the '048 reissue patent is a part of the bundle of rights upon which Teva had been the first to file); absent the '048 reissue patent, multiple generic makers would have been able to launch by May 31, 2014 without waiting for a sole Teva exclusivity to lapse or be forfeited.

227. If Pfizer had not filed and prosecuted the sham lawsuits claiming infringement of the invalid '048 reissue patent, those makers would have been able to launch generic celecoxib by May 31, 2014. Moreover, even if the PTO fraud allegations of this complaint fail at trial, the sham litigation against Teva would alone have caused delay of the entry generic celecoxib; absent the sham *Teva* litigation, (i) there would have been no settlement of the *Teva* litigation, (ii) Teva would not have made an agreement to wait to enter, (iii) it would have entered the market on or about May 31, 2014, and (iv) other generics (if stalled by Teva's resurrected first-to-file status) would still enter six months thereafter.

228. Teva received final FDA approval of its ANDA for generic celecoxib capsules on May 30, 2014. Teva has not launched its generic celecoxib product. Pfizer's wrongful conduct in procuring and litigating the '048 reissue patent is a "but for" cause of Teva's delay in the marketing of generic celecoxib capsules. Even though Teva has final FDA ANDA approval but

will not launch its generic product for at least many months in 2014, its failure to do so is unlikely to lead to forfeiture.[13]

229. Mylan received *tentative* FDA approval of its ANDA for generic celecoxib capsules on April 29, 2011 (three years ago). Mylan would have received *final* FDA on or about May 30, 2014 had it not been for the fraudulent procurement of the '048 reissue patent; it is the

[13] Teva's failure to do so is unlikely to lead to forfeiture. Teva submitted its ANDA to the FDA on November 13, 2003, prior to the enactment of the MMA on December 8, 2003. As a result, the section of the MMA providing for the forfeiture of a first applicant's 180-day exclusivity period, which now appears in § 505(j)(5)(B)(iv) of the FDCA, 21 U.S.C. § 355(j)(5)(B)(iv), does not apply. *See* Pub. L. 108-173, § 1102(b)(1), 117 Stat. 2066, 2460 (Dec. 8, 2003) ("Except as provided in paragraph (2), the amendment made by subsection (a) [amending Section 505(j)(5) of the FDCA, 21 U.S.C. 355(j)(5)] shall be effective only with respect to an application filed under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)) after the date of the enactment of this Act [Dec. 8, 2003] for a listed drug for which no certification under section 505(j)(2)(A)(vii)(IV) of that Act was made before the date of the enactment of this Act.").

Under the pre-MMA version of Hatch-Waxman, there were no provisions for forfeiture of exclusivity, and the relevant issue was the exclusivity period began or was "triggered." In the May 30, 2014 letter providing final approval for the Teva ANDA, the FDA stated that Teva's exclusivity "will begin to run from the earlier of the commercial marketing or court decision dates identified in section 505(j)(5)(B)(iv)." The pre-MMA version of § 505(j)(5)(B)(iv) of the FDCA provided:

> If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this subsection continuing such a certification, the application shall be made effective not earlier than one hundred and eighty days after—
>
> (I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
>
> (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed, whichever is earlier.

The MMA clarified that the term "decision of a court" used in this section means "a final decision of a court from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken." Pub. L. 108-173, § 1102(b)(3), 117 Stat. 2066, 2460 (Dec. 8, 2003). Even though the United States District Court for the Eastern District of Virginia has held that the '048 patent is invalid, that decision does not qualify as a "decision of a court" for the purposes of the pre-MMA version of § 505(j)(5)(B)(iv) and so it has not triggered Teva's 180-day exclusivity period.

Pfizer has appealed the district court's judgment of invalidity to the Federal Circuit. A decision by the Federal Circuit upholding the district court *would* trigger Teva's exclusivity period, allowing the FDA to approve other celecoxib ANDAs, and other generic manufacturers to bring generic celecoxib products to market, 180 days after the date of the Federal Circuit decision. However, the Federal Circuit is unlikely to issue such a decision before December 2014, the date on which Teva is permitted to launch its generic product under its agreement with Pfizer. Pfizer's opening brief in its appeal is not due to be filed until July 14, 2014. The appellees' briefs are not due until August 25, 2014, with Pfizer's reply due on September 8, 2014. Teva is not in danger of forfeiting or even shortening its exclusivity period by not launching its generic celecoxib product now, even though it has been cleared by the FDA to do so.

In short, through its unlawful procurement of the '048 patent and sham litigation to enforce that invalid patent, Pfizer has been able to delay generic competition well beyond even the date by which the FDA has granted final FDA approval for an ANDA product through, ironically, exploitation of *how long* ago the ANDA was filed.

existence of that patent that serves as the only reason that the FDA has ruled Teva entitled to sole first-to-file exclusivity, and it is only Teva's sole first-to-file status, and Pfizer's prosecution and settlement of sham litigation, that prevents FDA final approval of Mylan's generic product, and it is only FDA final approval that has prevents Mylan's immediate launch of generic celecoxib.

230. Watson received *tentative* FDA approval of its ANDA for generic celecoxib capsules on September 21, 2012 (almost two years ago). Watson would have received *final* FDA on or about May 30, 2014 had it not been for the fraudulent procurement of the '048 reissue patent; it is the existence of that patent that serves as the only reason that the FDA has ruled Teva entitled to sole first-to-file exclusivity, and it is only Teva's sole first-to-file status, and Pfizer's prosecution and settlement of sham litigation, that prevents FDA final approval of Watson's generic product, and it is only FDA final approval that has prevents Watson's immediate launch of generic celecoxib.

231. Even if a court concludes that Pfizer's procurement of the '048 reissue patent was not accomplished by the level of fraud required by law (and thus the '048 reissue patent may serve as a basis for Teva to have its sole first-to-file exclusivity resurrected), Pfizer's sham prosecution of the '048 patent litigations has caused significant delay of the launch of Teva's first-to-file product; as a consequence, it will delay the ability of FDA to give final ANDA approval to the Mylan and Watson ANDAs because FDA will need to wait 6 months after the eventual launch of Teva's product in order to then issue final approval to Mylan and Watson.

232. Similarly, even if an appellate court concludes that Teva is not entitled under law to have its sole first-to-file exclusivity resurrected, that ruling will only impact the number of generics that can at first enter the market and will not address the impact from Pfizer's sham litigations. Pfizer's wrongful conduct has already delayed generic entry of celecoxib and will

continue to do so until multiple generics enter the market and restore the market for celecoxib capsules to the rightful, competitive state.

233. Pfizer's anticompetitive conduct had the purpose and effect of restraining competition unreasonably and injuring competition by protecting Celebrex from generic competition. Pfizer's actions allowed it to maintain a monopoly and exclude competition in the market for celecoxib capsules, *i.e.*, Celebrex and its AB-rated generic equivalents.

234. Pfizer's exclusionary conduct has delayed generic competition and unlawfully enabled it to sell Celebrex without generic competition. But for the illegal conduct of Pfizer, Teva and one or more generic competitors would have begun marketing AB-rated generic versions of Celebrex sooner. By way of examples and not limitation: (i) if there had been no fraud upon the PTO, the '048 patents would not have issued, the patent would never have been listed in the Orange Book, and thus the patent would never have been the subject of infringement litigation; (ii) with no lawsuit, there would have been no settlements, which acted to further delay generic launch; and (iii) if the settlement agreement had not occurred, Teva would have entered the market on May 31, 2014, and other generics would have launched at that time or followed after Teva's sole 180-day exclusivity expired.

235. The generic manufacturers seeking to sell generic Celebrex had extensive experience in the pharmaceutical industry, including in obtaining approval for ANDAs, marketing generic pharmaceutical products, and manufacturing commercial launch quantities adequate to meet market demand, and at least several of these generic manufacturers would have been ready, willing and able to launch its generic version of Celebrex by May 31, 2014 were it not for Pfizer's illegal acts.

236. Pfizer's anticompetitive conduct, which delayed the introduction into the U.S. marketplace of any generic version of Celebrex, has caused and will cause Plaintiff and the Class to pay more than they would have paid for celecoxib capsules, absent this illegal conduct.

237. Typically, generic versions of brand-name drugs are initially priced significantly below the corresponding reference listed drug ("RLD") brand counterpart as to which they are AB-rated. As a result, upon generic entry, Class members' purchases of brand drugs are rapidly substituted for generic versions of the drug for some or all of their purchases. As more generic manufacturers enter the market, prices for generic versions of a drug predictably plunge even further because of competition among the generic manufacturers, and, correspondingly, the brand name drug continues to lose even more market share to the generic versions of the drug.

238. This price competition enables all purchasers of the drug to: (a) purchase generic versions of a drug at substantially lower prices; (b) purchase generic equivalents of the drug at a lower price, sooner; and/or (c) purchase the brand drug at a reduced price. Consequently, brand manufacturers have a keen financial interest in delaying and impairing generic competition, and purchasers experience substantial cost inflation from that delay and impairment.

239. If generic competitors had not been unlawfully prevented from entering the market earlier and competing with Pfizer, end-payor purchasers, such as Plaintiff and members of the Class, would have paid less for celecoxib capsules by (a) substituting purchases of less-expensive AB-rated generic Celebrex for their purchases of more-expensive brand Celebrex, (b) receiving discounts on their remaining brand Celebrex purchases, and/or (c) purchasing Celebrex at lower prices sooner.

240. Thus, the unlawful conduct of the defendants deprived Plaintiff and the Class of the benefits of competition that the antitrust laws were designed to ensure.

VIII. ANTITRUST IMPACT

241. During the relevant period, Plaintiff and members of the Class purchased substantial amounts of Celebrex indirectly from Pfizer. As a result of Pfizer's illegal conduct, members of the Class were compelled to pay, and did pay, artificially inflated prices for their celecoxib capsule requirements. Those prices were substantially greater than the prices that members of the Class would have paid absent the illegal conduct alleged herein, because: (1) the price of brand-name Celebrex was artificially inflated by the defendants' illegal conduct, and (2) Class members were deprived of the opportunity to purchase lower-priced generic versions of Celebrex sooner.

242. As a consequence, Plaintiff and members of the Class have sustained substantial losses and damage to their business and property in the form of overcharges. The full amount and forms and components of such damages will be calculated after discovery and upon proof at trial.

243. Pfizer's anticompetitive actions enabled it to indirectly charge consumers and third-party payors prices in excess of what it otherwise would have been able to charge absent its unlawful actions.

244. The prices were inflated as a direct and foreseeable result of Pfizer's anticompetitive conduct.

245. The inflated prices the Class paid are traceable to, and the foreseeable result of, the overcharges by Pfizer.

246. At all relevant times, Pfizer manufactured, promoted, distributed, and sold substantial amounts of Celebrex in a continuous and uninterrupted flow of commerce across state and national lines throughout the United States.

247. At all material times, Defendants transmitted funds, as well as contracts, invoices and other forms of business communications and transactions, in a continuous and uninterrupted flow of commerce across state and national lines in connection with the sale of Celebrex and their generic equivalents.

248. In furtherance of their efforts to monopolize and restrain competition, Defendants employed the United States mails and interstate and international telephone lines, as well as means of interstate and international travel. Defendants' activities were within the flow of, and have substantially affected (and will continue to substantially effect), interstate commerce.

249. Defendants' anticompetitive conduct also had substantial intrastate effects in that, *inter alia*, retailers within each state were foreclosed from offering cheaper generic Celebrex to end-payors inside each respective state. The complete foreclosure of generic Celebrex directly impacted and disrupted commerce for end-payors within each state (and will continue to do so).

IX. CLASS ALLEGATIONS

250. Plaintiff, on behalf of itself and all members of the Classes, seek damages, measured as overcharges, against Pfizer based on allegations of anticompetitive conduct in the market for Celebrex.

251. Plaintiff brings this action on behalf of itself and, under Fed. R. Civ. P. 23(a) and (b)(3), as a representative of the below-defined Class (the "Class" or the "End-Payor Class") defined as follows:[14]

> All persons or entities who purchased and/or paid for some or all of the purchase price for Celebrex and/or its AB-rated generic equivalents in Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, Delaware, Florida, Georgia, Hawai'i, Idaho, Illinois, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana,

[14] For purposes of the class definitions, persons or entities "purchased" Celebrex or its generic equivalent if they paid or reimbursed some or all of the purchase price.

> Nebraska, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, Washington, West Virginia, Wisconsin, Wyoming, and the District of Columbia and Puerto Rico (the "Class States"), in any form, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale, during the period May 31, 2014, through and until the anticompetitive effects of Defendants' unlawful conduct ceases (the "Class Period").

252. The following persons or entities are excluded from the proposed End-Payor Class:

a. Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;

b. All governmental entities, except for governmental funded employee benefit plans;

c. All persons or entities who purchased Celebrex for purposes of resale or directly from Defendants or their affiliates;

d. Fully insured health plans (*i.e.*, Plans that purchased insurance from another third-party payor covering 100% of the Plan's reimbursement obligations to its members);

e. Pharmacy benefit managers without capitation contracts; and

f. The judges in this case and any members of their immediate families.

253. Members of the End-Payor Class are so numerous that joinder is impracticable. Plaintiff believes that the Class includes hundreds of thousands, if not millions, of consumers, and thousands of third-party payors.

254. Plaintiff's claims are typical of the claims of the members of the End-Payor Class. Plaintiff and all members of the End-Payor Class were damaged by the same wrongful conduct of Pfizer, *i.e.*, they paid artificially inflated prices for Celebrex and were deprived of the benefits of earlier and more robust competition from cheaper generic versions of Celebrex as a result of Defendants' wrongful conduct.

255. Plaintiff will fairly and adequately protect and represent the interests of the End-Payor Class. Plaintiff's interests are coincident with, and not antagonistic to, those of the End-Payor Class.

256. Plaintiff is represented by counsel with experience in the prosecution of class action antitrust litigation, and with particular experience with class action antitrust litigation involving pharmaceutical products.

257. Questions of law and fact common to the members of the End-Payor Class predominate over questions that may affect only individual Class members because Pfizer has acted on grounds generally applicable to the entire End-Payor Class, thereby making overcharge damages with respect to the End-Payor Class as a whole appropriate.

258. Questions of law and fact common to the End-Payor Class include, but are not limited to:

a. whether Pfizer willfully obtained and/or maintained monopoly power over Celebrex and its generic equivalents;

b. whether Prizer obtained the '048 reissue patent by fraud;

c. whether Pfizer unlawfully excluded competitors and potential competitors from the market for Celebrex and its AB-rated generic bioequivalents;

d. whether Pfizer unlawfully delayed or prevented generic manufacturers of celecoxib from coming to market in the United States;

e. whether Pfizer maintained monopoly power, itself and/or in conspiracy with Teva and/or Watson, by delaying generic entry;

f. whether the defendants entered into an illegal contract, combination, conspiracy and/or other agreement in restraint of trade;

g. whether the law requires definition of a relevant market when direct proof of monopoly power is available, and if so the definition of the relevant market;

h. whether the Defendants' activities as alleged herein have substantially affected interstate commerce;

i. whether, and if so to what extent, the defendants' conduct caused antitrust injury (*i.e.*, overcharges) to Plaintiff and the members of the Class; and

j. the quantum of aggregate overcharge damages to the Class.

259. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

260. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

X. CLAIMS FOR RELIEF

COUNT I
FOR MONOPOLIZATION UNDER STATE LAW
(Asserted Against Pfizer)

261. Plaintiff repeats and incorporates by reference all preceding paragraphs and allegations.

262. As described above, from January 1999 until the present, and with effects that will continue, Pfizer possessed and possesses monopoly power in the market for celecoxib capsules. No other manufacturer sells a competing version of celecoxib in the United States.

263. Pfizer has willfully and unlawfully maintained its monopoly power in the celecoxib capsule market from May 30, 2014 through the present by engaging in an anticompetitive scheme to keep generic equivalents from the market—not as a result of providing a superior product, business acumen, or historical accident.

264. Pfizer knowingly and intentionally engaged in an anticompetitive scheme designed to block and delay entry of AB-rated generic versions of Celebrex to maintain its monopoly power. This scheme included:

a. obtaining the '048 patent by fraud through misleading the PTO and failing to exercise the duty of good faith;

b. improperly listing the '048 patent in the Orange Book;

c. engaging in sham litigation; and

d. prolonging the impact of its sham litigation through settlement arrangements, requiring, by definition, concerted activity with others that further delayed generic entry.

265. By engaging in the foregoing conduct, Pfizer has intentionally and wrongfully maintained monopoly power in the relevant market in violation of the following state laws:

a. Arizona Rev. Stat. §§ 44-1403, *et seq.*, with respect to purchases in Arizona by members of the Class.

b. Cal. Bus. & Prof. Code §§ 17200, *et seq.*, and §§ 16700, *et seq.*, with respect to purchases in California by members of the Class.

c. D.C. Code §§ 28-4503, *et seq.*, with respect to purchases in the District of Columbia by members of the Class.

d. Fla. Stat. §§ 501.201, *et seq.*, with respect to purchases in Florida by members of the Class.

e. 740 Ill. Comp. Stat. 10/3, *et seq.*, with respect to purchases in Illinois by members of the Class.

f. Iowa Code § 553.5, *et seq.*, with respect to purchases in Iowa by members of the Class.

g. Mass. Gen. L. Ch. 93A, *et seq.*, with respect to purchases in Massachusetts by members of the Class, with thousands of Massachusetts end-payors paying substantially higher prices for delayed-release esomeprazole magnesium in actions and transactions occurring substantially within Massachusetts.

h. Me. Rev. Stat. Ann. 10, §§ 1102, *et seq.*, with respect to purchases in Maine by members of the Class.

i. Mich. Comp. Laws Ann. §§ 445.773, *et seq.*, with respect to purchases in Michigan by members of the Class.

j. Minn. Stat. §§ 325D.52, *et seq.*, and Minn. Stat. § 8.31, *et seq.*, with respect to purchases in Minnesota by members of the Class.

k. Miss. Code Ann. §§ 75-21-3, *et seq.*, with respect to purchases in Mississippi by members of the Class.

l. Neb. Code Ann. §§ 59-802, *et seq.*, with respect to purchases in Nebraska by members of the Class.

m. Nev. Rev. Stat. Ann. §§ 598A.060, *et seq.*, with respect to purchases in Nevada by members of the Class.

n. N.M. Stat. Ann. §§ 57-1-2, *et seq.*, with respect to purchases in New Mexico by members of the Class.

o. New York General Business Law § 340, *et seq.*, with respect to purchases in New York by members of the Class.

p. N.C. Gen. Stat. §§ 75-2.1, *et seq.*, with respect to purchases in North Carolina by members of the Class.

q. N.D. Cent. Code §§ 51-08.1-03, *et seq.*, with respect to purchases in North Dakota by members of the Class.

r. Or. Rev. Stat. §§ 646.705, *et seq.*, with respect to purchases in Oregon by members of the Class.

s. 10 L.P.R.A. § 260, *et seq.*, with respect to purchases in Puerto Rico by members of the Class.

t. S.D. Codified Laws §§ 37-1-3.2, *et seq.*, with respect to purchases in South Dakota by members of the Class.

u. Utah code Ann. §§ 76-10-911, *et seq.*, with respect to purchases in Utah by members of the Class.

v. Vt. Stat. Ann. 9, §§ 2453, *et seq.*, with respect to purchases in Vermont by members of the Class.

w. W.Va. Code §§ 47-18-4, *et seq.*, with respect to purchases in West Virginia by members of the Class.

x. Wis. Stat. §§ 133.03, *et seq.*, with respect to purchases in Wisconsin by members of the Class.

266. Plaintiff and members of the Class have been injured in their business or property by reason of Defendants' antitrust violations alleged in this Claim. Their injuries consist of: (1) being denied the opportunity to purchase lower-priced generic Celebrex products, and (2) paying higher prices for Celebrex products than they would have paid in the absence of Defendants' conduct. These injuries are of the type the laws of the above States, the District of Columbia, and Puerto Rico were designed to prevent, and flow from that which makes Defendants' conduct unlawful.

267. Plaintiff and the Class seek damages and multiple damages as permitted by law for their injuries by Defendants' violations of the aforementioned statutes.

COUNT II
UNJUST ENRICHMENT
(Asserted Against Pfizer)

268. Plaintiff repeats and incorporates by reference all preceding paragraphs and allegations.

269. It would be inequitable under the laws of all states and jurisdictions within the United States, except for Indiana and Ohio, for Defendants to retain any of the overcharges for Celebrex derived from Defendant's unfair and unconscionable methods, acts, and trade practices alleged herein.

270. Pfizer has benefited from the monopoly profits on their sales of Celebrex resulting from the unlawful and inequitable acts alleged in this Complaint.

271. Pfizer's financial benefits resulting from their unlawful and inequitable conduct are traceable to overpayments for Celebrex by Plaintiff and members of the Class.

272. Plaintiff and the Class have unknowingly conferred upon Pfizer an economic benefit, in the nature of profits resulting from unlawful overcharges and monopoly profits, to the economic detriment of Plaintiff and the Class.

273. The economic benefit of overcharges and unlawful monopoly profits derived by Pfizer through charging supracompetitive and artificially inflated prices for Celebrex is a direct and proximate result of Pfizer's unlawful practices.

274. The financial benefits derived by Pfizer rightfully belong to Plaintiff and the Class, as Plaintiff and the Class paid anticompetitive and monopolistic prices during the Class Period, inuring to Pfizer's benefit.

275. It would be inequitable for Pfizer to be permitted to retain any of the overcharges for Celebrex derived from Pfizer's unfair and unconscionable methods, acts and trade practices alleged in this Complaint.

276. Pfizer should be compelled to disgorge in a common fund for the benefit of Plaintiff and the Class all unlawful or inequitable proceeds received by Pfizer.

277. To the extent the Court finds that Plaintiff and the Class members have no adequate remedy at law, a constructive trust should be imposed upon all unlawful or inequitable sums received by Pfizer traceable to Plaintiff and the Class.

COUNT III
DECLARATORY AND INJUNCTIVE RELIEF
(Asserted Against Pfizer)

278. Plaintiff repeats and incorporates by reference all preceding paragraphs and allegations.

279. Plaintiff's allegations described herein and in the preceding Counts comprise violations of Sections 1 and 2 of the Sherman Act, in addition to the state laws *supra*.

280. Plaintiff and the Class, pursuant to Fed. R. Civ. P. 57 and 28 U.S.C. § 2201(a), hereby seek a declaratory judgment that Pfizer's conduct in seeking to prevent competition as described herein violates Sections 1 and 2 of the Sherman Act.

281. Plaintiff and the Class further seek equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by the unlawful conduct of Pfizer, and other relief so as to assure that similar anticompetitive conduct does not reoccur in the future.

XI. DEMAND FOR JUDGMENT

282. WHEREFORE, IUOE Local 49 Fund, on behalf of itself and the Class, respectfully requests that the Court:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3), and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2), be given to the Class; find IUOE Local 49 Fund to be an adequate representative of the class; and appoint the undersigned attorneys as Class Counsel;

B. Conduct expedited discovery proceedings leading to a prompt trial on the merits before a jury on all claims and defenses;

C. Enter joint and several judgments against the defendants and in favor of IUOE Local 49 Fund and the Class;

D. Award the Class damages (*i.e.*, three times overcharges, to the extent allowed by applicable law) in an amount to be determined at trial, plus interest in accordance with law;

E. Award IUOE Local 49 Fund and the class their costs of suit, including reasonable attorneys' fees as provided by law; and

F. Award such further and additional relief as is necessary to correct for the anticompetitive market effects caused by Pfizer's unlawful conduct, as the Court may deem just and proper under the circumstances.

XII. JURY DEMAND

283. Pursuant to Fed. Civ. P. 38, Plaintiff, on behalf of itself and the proposed class, demands a trial by jury on all issues so triable.

Dated: July 9, 2014

Respectfully submitted,

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